EDITOR'S NOTE

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tober 18, 1985

Title: Frank Young, Commissioner of Food and Drug Administration, Petitioner
v.
Community Nutrition Institute, et al.

Court: United States Court of Appeals for the District of Columbia Circuit

Counsel for petitioner: Solicitor General

Counsel for respondent: Schultz, William B.

try	Date	Note	Proceedings and Orders
1	Aug 9 1985		Application for extension of time to file petition and order granting same until October 20, 1985 (Brennan, August 13, 1985).
2	Oct 18 1985	G	Petition for writ of certiorari filed.
3	Nov 18 1985		Brief of respondent Community Nutrition Institute in opposition filed.
4	Nov 18 1985		Brief amicus curiae of National Peanut Council, Inc. filed.
5	Nov 19 1985		Brief amicus curiae of South Carolina filed.
6	Nov 19 1985		Brief amicus curiae of Natl. Food Processors Assn. filed.
7	Nov 20 1985		DISTRIBUTED. December 6, 1985
8	Nov 20 1985		Brief amicus curiae of American Feed Industry Association, et al. filed.
9	Nov 20 1985	X	Brief amicus curiae of Grocery Manufacturers of America, Inc. filed.
0	Dec 9 1985		Petition GRANTED.
			**********
2	Jan 13 1986		Order extending time to file brief of petitioner on the merits until February 7, 1986.
3	Jan 24 1986		Brief amicus curiae of National Food Processors Assn. filed.
4	Feb 7 1986		Brief amicus curiae of National Peanut Council, Inc. filed.
5	Feb 7 1986		Brief amicus curiae of Grocery Manufacturers of America, Inc. filed.
6	Feb 7 1986		Brief amicus curiae of American Feed Industry Association filed.
7	Feb 7 1986		Brief amicus curiae of South Carolina filed.
8	Feb 10 1986		Joint appendix filed.
9	Feb 10 1986		Brief of petitioner Commr., FDA, Young filed.
0	Feb 26 1986		Record filed.
1	Feb 26 1986		Certified copy of original record and proceedings received.
3	Mar 6 1986		Order extending time to file brief of respondent on the merits until March 14, 1986.
4	Mar 14 1986		SET FOR ARGUMENT, Wednesday, April 30, 1986. (3rd case)
5	Mar 14 1986		Brief of respondents Community Nutrition Inst., et al. filed.
6	Mar 27 1986		CIRCULATED.
7	Apr 23 1986	X	Reply brief of petitioner Commr., FDA, Young filed.
8	Apr 30 1986		ARGUED.

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CLERK

No. 85-664

In the Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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BEST AVAILABLE COPY

QUESTION PRESENTED

Whether the Food and Drug Administration is required to regulate unavoidable "added" poisonous or deleterious substances in food by means of formal rulemaking pursuant to 21 U.S.C. 342(a)(2)(A), rather than by case-by-case adjudication pursuant to 21 U.S.C. 342(a)(1).

PARTIES TO THE PROCEEDING

The petitioner is Frank Young, Commissioner of Food and Drugs. The respondents are the Community Nutrition Institute, Public Citizen, and Linda S. Bardot.

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In the Supreme Court of the United States

OCTOBER TERM, 1985

No.

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The Solicitor General, on behalf of the Commissioner of Food and Drugs, petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-16a) is reported at 757 F.2d 354. The May 1, 1985 order amending the court of appeals' opinion (App., *infra*, 17a) and the opinion of the district court (App., *infra*, 21a-34a) are unreported.

JURISDICTION

The judgment of the court of appeals (App., *infra*, 35a) was entered on March 26, 1985. A petition for rehearing was denied on May 23, 1985 (App., *infra*, 18a). By order dated August 13, 1985, Justice Brennan extended the time within which to file a petition for a writ of certiorari to and including October 20, 1985. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Sections 402(a), 406, and 701(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a), 346, and 371(e), and 21 C.F.R. 509.6(b)-(c) are reproduced at App., *infra,* 36a-40a.

STATEMENT

This case concerns the procedures that the Food and Drug Administration (FDA) must employ in regulating the presence in food of any added poisonous or deleterious substance that is required in the production of the food or that cannot be avoided by good manufacturing practice. The specific substance at issue here is "aflatoxin," a carcinogenic mold byproduct that commonly grows on corn and other crops. Since the enactment of the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938, the FDA has regulated the amounts of substances like aflatoxin principally by issuing what the FDA terms "action levels." These "action levels" announce the level of the particular substance that the FDA regards as resulting in adulteration under 21 U.S.C. 342(a)(1). In this case, the court of appeals upset this longstanding administrative interpretation of the FDCA and held that the FDA must instead set tolerances by time-consuming and burdensome formal rulemaking procedures.

1. *Statutory and Regulatory Scheme.* The FDCA, 21 U.S.C. 331, prohibits the shipment in interstate commerce of "adulterated" food. Under 21 U.S.C. 342, a food is deemed to be adulterated if either of two conditions is met. The first, Section 342(a)(1), applies to all poisonous substances, whether inherent in the food or "added" to it, and provides that a food is adulterated if it contains "any poisonous or deleterious substance which may render it injurious to health." The second, Section 342(a)(2)(A), applies only to "added" poisons and states that food is adulterated if it contains any "added poisonous or added deleterious substance * * * which is unsafe within the

meaning of" 21 U.S.C. 346. Aflatoxin is regarded as an added poison because it is added by mold, *i.e.*, it is not an inherent constituent of food.

Section 346 defines when a food with an added poison is "unsafe" within the meaning of that provision. The first clause of Section 346 provides that any added poison renders the food unsafe unless its presence "is required in the production thereof or cannot be avoided by good manufacturing practice * * *." Since aflatoxin falls within this exception, food containing aflatoxin is not rendered "unsafe" by this clause. Section 346 next addresses the question of when a food to which a required or unavoidable poison, like aflatoxin, has been added is deemed to be unsafe. The statute provides in pertinent part:

> [W]hen such substance is so required or cannot be so avoided, the Secretary [of Health and Human Services] shall promulgate regulations limiting the quantity therein or thereon to such entent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of [Section 342(a)(2)(A)].

For nearly a half-century, the FDA has interpreted these provisions as allowing it to regulate substances such as aflatoxin either by structuring its discretion to bring enforcement actions under Section 342(a)(1) or by issuing formal regulations pursuant to Sections 342(a)(2)(A) and 346. If the FDA elects to proceed under Section 342(a)(1), the government must establish in an enforcement proceeding that the level of the substance present may render the food injurious to health. This is the option that the FDA has used with respect to aflatoxin, and the FDA has adopted an action level to aid the agency in the exercise of

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[1] Since 1969, the action level for aflatoxin in human food or animal feed has been 20 parts per billion. App., *infra,* 22a.

its prosecutorial discretion.[1] In the alternative, FDA may promulgate a Section 346 tolerance. Once a tolerance is in effect, the government in an enforcement proceeding need only establish that the tolerance has been violated; it need not adduce independent evidence that the food may be injurious to health. See 21 U.S.C. 346.

The procedures employed in promulgating action levels differ significantly from those required for issuance of tolerances. Action levels are not subject to notice-and-comment rulemaking under the Administrative Procedure Act. However, the FDA does publish a notice in the *Federal Register* announcing the new level and the availability of all the relevant data, and it invites public comment. 42 Fed. Reg. 52817 (1977). By contrast, 21 U.S.C. 371(e) prescribes a formal and complicated procedure for the issuance of regulations setting tolerances under Section 346. Within 30 days after publication of a final regulation in the *Federal Register,* any party who may be adversely affected may file objections and request a public hearing. 21 U.S.C. 371(e)(2). The filing of such objections stays the effectiveness of the proposed regulation until the Secretary of Health and Human Services takes final action on the objections. *Ibid.* If the objections raise genuine and substantial factual issues, the Secretary, after providing further notice in the *Federal Register,* must conduct a public hearing at which "any interested person may be heard in person or by representative." 21 U.S.C. 371(e)(3). The Secretary must then rule on the objections, setting forth "detailed findings of fact." *Ibid.* Except in emergencies, the regulation may not take effect until 90 days after the Secretary's decision (*ibid.*), which is subject to judicial review (21 U.S.C. 371(f)).

In determining whether to issue informal action levels or formal tolerances in a particular case, the FDA takes these procedural differences into account. FDA regulations provide for the use of action levels when it is impracticable to

set tolerances. See 21 C.F.R. Pt. 109 (human food); 21 C.F.R. Pt. 509 (animal food). For example, action levels rather than tolerances are to be used when changes in the capabilities of good manufacturing practices are expected or when the results of ongoing studies might provide significant new toxicological data or other data that might render a tolerance obsolete. 21 C.F.R. 509.6(b)-(c).

2. *Proceedings Below.* Respondents (two public interest groups and a consumer) brought this suit in the United States District Court for the District of Columbia to challenge the FDA's regulation of aflatoxin. Respondents contended (1) that the FDA should be compelled to adopt a formal aflatoxin tolerance pursuant to Section 346, as opposed to an informally implemented action level (2) that the action level, in the alternative, should be made subject to notice-and-comment rulemaking, and (3) that certain exemptions to the action level were contrary to law. The district court granted summary judgment in favor of the FDA on all three issues. Recognizing that an agency's interpretation of its statute is entitled to substantial deference, the court found that the FDA's construction of Section 346 was reasonable and that Section 346 "confers discretionary, not mandatory, authority on the agency to establish tolerances." App., *infra,* 31a-32a (footnote omitted). It also concluded that "action levels" were general statements of policy not requiring notice-and-comment rulemaking and that the exemptions granted were within the agency's discretion. *Id.* at 32a-34a.

The court of appeals reversed, holding that "the FDA may not proceed by means of action levels rather than tolerances" (App., *infra,* 2a).[2] In reaching this conclusion, the court relied heavily on its parsing of the second

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[2] Because the court of appeals reversed on this ground, it did not consider respondents' other claims (App., *infra,* 2a).

sentence of Section 346, which, as noted, provides that when an added poisonous or deleterious substance is "required" or "cannot be * * * avoided"

> the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health.

The court refused to accept (App., *infra,* 6a) the FDA's interpretation of this provision, *i.e.,* that the Secretary is obligated to promulgate formal regulations only " 'to such extent as [he] finds necessary for the protection of public health' " and may employ informal action levels in all other circumstances. Instead, the court found (*id.* at 7a) that it was "clear from the structure of the sentence * * * that the phrase relied upon by the Secretary simply does not modify the pivotal word 'shall' " but, rather, "explains the standard that the Secretary is to employ in setting the tolerance."

The court of appeals found additional support for its interpretation in an argument that seems to suggest that much of the nation's food supply is "adulterated" within the meaning of the FDCA. The court interpreted (App., *infra,* 7a) Section 346 to mean that any food to which an unavoidable poisonous or deleterious substance has been added is adulterated unless "a regulation establishing a tolerance is in effect." The court reasoned (App., *infra,* 7a):

> Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce.

The court of appeals advanced no other arguments to buttress its interpretation. It found "little guidance in the legislative history" (App., *infra,* 9a), and it did not cite any supporting judicial authority, but instead merely attempted to distinguish the cases upon which the FDA relied (*id.* at 11a-15a).

REASONS FOR GRANTING THE PETITION

In the production of food, it is often impossible to avoid the presence of small quantities of added substances that may be harmful to human health if taken in sufficient amount. For nearly 50 years, the FDA has regulated the presence of such substances in food principally by issuing informal "action levels" and by enforcing these standards through litigation under Section 342(a)(1) of the FDCA. This informal procedure has allowed the FDA to move quickly in response to health hazards; it has provided flexibility in an area in which the relevant scientific data and the capabilities of good manufacturing processes are subject to frequent changes; and it has permitted the FDA, by limiting burdensome and unproductive formal rulemaking proceedings, to allocate its scarce resources to activities of greater value in safeguarding the public health.

The court of appeals' decision, which upsets this settled and successful practice, threatens to squander administrative resources and to impair the FDA's ability to act expeditiously and respond to changed conditions in this important area. The court's reasoning also suggests that much of the nation's food supply is now and will remain "adulterated" within the meaning of the FDCA until formal regulations setting tolerances are issued—a process that is certain to take years, if not decades, to complete. For these reasons, this case concerns a matter of substantial importance that warrants this Court's review.

1. a. An agency's interpretation of the statute it is charged with administering is "entitled to considerable deference." *Chemical Manufacturers Ass'n* v. *NRDC,* No. 83-1013 (Feb. 27, 1985), slip op. 8. "[T]o sustain it, [a court] need not find that it is the only permissible construction that [the agency] might have adopted but only that [the agency's] understanding * * * is a sufficiently rational one to preclude a court from substituting its judgment for that of [the agency]." *Id.* at 8-9. See also

Chevron U.S.A. Inc. v. *NRDC,* No. 82-1005 (June 25, 1984), slip op. 4-7; *United States* v. *Rutherford,* 442 U.S. 544, 553-554 (1979); *Train* v. *NRDC,* 421 U.S. 60, 75 (1975). Under this standard, the FDA's interpretation of the relevant provisions of the FDCA should have been sustained.

As the court of appeals recognized, the pivotal statutory provision is the second sentence of 21 U.S.C. 346, which provides that when any added poisonous or deleterious substance is "required" in the production of food or "cannot be avoided by good manufacturing practice,"

> the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health * * *.

In the FDA's view, the phrase "to such extent as he finds necessary for the protection of public health" modifies the verb "shall." Accordingly, the FDA has consistently interpreted this provision to mean that it must promulgate regulations only if it finds that they are necessary for the protection of public health.

The court of appeals, by contrast, concluded that the critical phrase "to such extent as he finds necessary for the protection of public health" modifies the participle "limiting." Thus, in the court's view, the FDA must promulgate regulations establishing tolerances for *all* added poisonous or deleterious substances that cannot practicably be avoided in food production, and these regulations must "limit[ ] the quantity" of such substances "to such extent as [the FDA] finds necessary for the protection of public health."

Both interpretations of the statutory language are entirely rational and plausible. Therefore, the statutory language provides no basis for overriding the FDA's longstanding construction of the statute it has been entrusted by Congress with administering, especially in view of the statute's complexity. See *Pattern Makers* v. *NLRB*, No. 83-1894 (June 27, 1985), slip op. 19; *Chemical Manufacturers Ass'n*, slip op. 8. Even if the court of appeals believed that its own interpretation of the statutory language corresponded with the most refined rules regarding the proper placement of modifiers, that alone was not a sufficient reason for refusing to defer to the FDA's interpretation. After all, complex regulatory statutes like the FDCA often appear to be written in a language that is all their own, and thus adherence to the highest standards of normal usage is not always a reliable way to divine Congress's intent.

b. Not only is the language of Section 342(a)(1) insufficient to support the court of appeals' interpretation, but that interpretation is critically undermined by the overall structure of the statutory scheme. It is a cardinal rule of statutory interpretation that a statute should be construed so as to give effect to all of its provisions. See, *e.g.*, *Dickerson* v. *New Banner Institute, Inc.*, 460 U.S. 103, 118 (1983). Here, FDA's construction satisfies this canon, while the court of appeals' interpretation makes Section 342 (a)(1) superfluous for "added" substances, like aflatoxin, even though Section 342(a)(1) was expressly intended to play a role in the regulation of such substances.[3]

Under Section 346, the addition of a poisonous or deleterious substance automatically renders a food "unsafe" (and thus "adulterated" under Section 342(a)(2)) unless the added substance is "required" or cannot practicably be avoided. Thus, it is undisputed that Section 342(a)(1) is not needed to regulate substances that are not required or are avoidable in food production. This obviously leaves only those added substances that are required or cannot practicably be avoided. As previously noted, FDA's view is that it may regulate the occurrence of these substances either by issuing action levels and bring-

[3] Section 342(a)(1) states that "*in case the substance is not an added substance* such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health" (emphasis added). This sentence makes clear that Section 342(a)(1) was meant to govern both added and inherent substances.

ing suit in appropriate cases under Section 342(a)(1) (in which case the FDA must prove in court that the added substance renders the food "injurious to health") or by promulgating formal regulations under Section 346 (in which case any food exceeding those tolerances is automatically deemed to be unsafe and adulterated). Cf. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). This interpretation assigns an important role to both Section 342(a)(1) and Section 342(a)(2).

Under the court of appeals' interpretation, however, FDA must issue formal regulations for all such substances. Once such regulations are promulgated, Section 342(a)(1) has no role to play. If a food is "unsafe" under Section 342(a)(2)(A) by virtue of a formal regulation, FDA would have no need to proceed under Section 342(a)(1), which requires proof in court of injury to health. And if a food is deemed to be "safe" under such a regulation, Section 346 expressly provides that the food "shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated" under Section 342(a)(1).[4]

c. The language and structure of the FDCA thus provide substantial support for the FDA's long-settled construction of the statute. Indeed, the FDA's interpretation is entitled to enhanced deference because Congress has specifi-

[4] Besides its parsing of the second sentence of Section 346, the court of appeals' only ground for its decision was the belief that a food containing a substance such as aflatoxin is adulterated and thus cannot be shipped in interstate commerce unless a regulation establishing a tolerance is in effect. App., *infra*, 7a. This interpretation of the statute is mistaken. To be sure, if a tolerance has been set, a food containing a substance such as aflatoxin is unsafe and adulterated under Sections 342(a)(2) and 346 unless the tolerance is met. But neither these nor any other provisions of the FDCA provide that a food containing a substance like aflatoxin is unsafe or adulterated if no tolerance is in effect. In that situation, Sections 342(a)(2) and 346 are silent. Section 342(a)(1) is then the governing provision, and the food is considered to be adulterated only if it can be shown to be "injurious to health."

cally noted that interpretation while considering revisions of the FDCA but has done nothing to alter the administrative practice. See *Haig* v. *Agee*, 453 U.S. 280, 297-298 (1981); *Chemehuevi Tribe of Indians* v. *FPC*, 420 U.S. 395, 410 (1975); *NLRB* v. *Gullett Gin Co.*, 340 U.S. 361, 366 (1951).

Under the FDCA, pesticide residues in food were originally governed by Section 346, but in 1954 Congress enacted a new provision, 21 U.S.C. 346a, to regulate the presence of pesticide residues in raw agricultural products. During the hearings preceding passage of this legislation, both the Commissioner of Food and Drugs and industry representatives called the FDA's position to Congress's attention,[5] and this interpretation not only was expressly

[5] The FDA Commissioner, Charles W. Crawford, stated (*Federal Food Drug, and Cosmetic Act: Hearing on H.R. 4277 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. 121 (1953):

> We have given out so-called informal tolerances on a great many of these things, we have freely given that out and if their schedules bring those spray residues within those informal tolerances there is no basis under the law for us to proceed because if we proceed on the other provision of section 402 [21 U.S.C. 342]—that is 402(a)(1) [21 U.S.C. 342(a)(1)], we have to assume the burden of proving that the quantity of the spray residue present in this particular commodity here in and of itself may injure the health of consumers and we would not give a tentative tolerance at a figure where there was any likelihood of our being able to make a case of that kind.

The National Canners Association wrote to both the House and Senate committees to express its understanding that Section 408 (21 U.S.C. 346a) would apply only to raw agricultural products. The Association's letter to the House committee stated (*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 2d Sess. 31 (1954) (emphasis added)):

> It is the understanding of the National Canners Association that after passage of this bill processed foods will be in exactly the same position as before in that *tolerances for pesticide residues*

noted by both the House and Senate committees but appears to have played an important part in their thinking. See H.R. Rep. 1385, 83d Cong., 2d Sess. 2, 6-7 (1954); S. Rep. 1635, 83d Cong., 2d Sess. 6 (1954). The House Report observed that while the law "authorizing" the issuance of formal tolerances had been in effect for more than 15 years, "[d]uring all that time control has been exercised through unofficial and informal tolerances." H.R. Rep. 1385, *supra,* at 2. The Report continued (*id.* at 2-3) that in 1950 "lengthy public hearings," costing nearly $500,000, had been held for the purpose of establishing official tolerances for pesticide residues in fresh fruits and vegetables but that official tolerances still had not been promulgated due to "the cumbersome, time-consuming, and impracticable procedure prescribed by existing law." To overcome these difficulties, the House committee recommended (*id.* at 2) "an improved procedure for establishment of tolerances for pesticide chemicals remaining in or on raw agricultural commodities." The Senate Report (S. Rep. 1635, *supra,* at 6) made the identical points.

Thus, the congressional committees expressly observed that the FDA was relying chiefly on informal rather than formal tolerances, yet they did not suggest that this practice was unlawful or undesirable and did nothing to require its abandonment in favor of exclusive reliance on formal rulemaking. On the contrary, the committees sharply criticized the formal statutory procedure set out in the FDCA Act and crafted a new, simpler, and speedier method for rectifying the problem caused by the breakdown of the formal procedure in the field of pesticide residues on raw agricultural products. This is powerful evidence that Congress approved the FDA's interpretation of the statutory provisions at issue here.

2. The court of appeals' interpretation of these provisions is inconsistent with that of the Fifth Circuit in *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149 (1979), an action to enjoin shipment of grain containing an amount of aflatoxin exceeding the FDA's action level. There, the Fifth Circuit expressly adopted the interpretation of the relevant statutory provisions that the D.C. Circuit rejected in this case. The Fifth Circuit wrote (*id.* at 151):

> In implementing the Act, the FDA either may adopt formal regulations, 21 U.S.C. § 346, or may litigate alleged violations on a case-by-case basis. * * * To guide its prosecutorial discretion in the bringing of non-rule enforcements of the Act the FDA may establish certain in-house guidelines called action levels.

Holding that the grain at issue was adulterated, the court noted (*ibid.*) that it had "evolved a policy of considerable deference to agency action levels." See also *United States* v. *Anderson Seafoods, Inc.*, 447 F. Supp. 1151, 1153 n.2 (N.D. Fla. 1978), aff'd, 622 F.2d 157 (5th Cir. 1980).

The D.C. Circuit in the present case distinguished *Boston Farm Center* (App., *infra,* 11a-12a) on the ground that it concerned the FDA's authority to enjoin shipment of adulterated grain without issuing a formal tolerance and did not address the FDA's obligation to issue a formal tolerance. This is an exceedingly narrow distinction that

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with respect to processed foods may be established under section 406 [21 U.S.C. 346] of the Act; that in the event the Secretary acts to establish a tolerance for residues on processed foods under section 406 actions for adulteration will be taken under section 402(a)(2) but *if the Secretary has not acted under section 406 any action for adulteration because of excessive pesticide residue in the processed food will still be taken under section 402(a)(1)* [21 U.S.C. 342(a)(1)]. This understanding of the canning industry is, we are advised, shared by Dr. Miller [*i.e.*, Representative Miller, the sponsor of the House bill], by the FDA, and by all others interested in this legislation.

See also *Residues of Pesticide Chemicals: Hearing on S. 2868 and H.R. 7125 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 83d Cong., 2d Sess. 93 (1954) (NCA letter to the Senate committee chairman to the same effect).

cannot camouflage the fact that the two circuits interpret the statutory provisions in ways that are fundamentally irreconcilable. While the D.C. Circuit held (App., *infra,* 2a) that "the FDA may not proceed by means of action levels rather than tolerances," the Fifth Circuit in *Boston Farm Center* expressly recognized (590 F.2d at 151) that the FDA had the discretion to follow either procedure. Moreover, it would be patently inconsistent to hold, as the court below did, that FDA action levels are unlawful substitutes for formal tolerances while at the same time to hold, as the Fifth Circuit did in *Boston Farm Center,* that the distribution of grain may be enjoined based upon "considerable deference" to the FDA's action level. Surely the distributor in *Boston Farm Center,* who stood to suffer considerable economic loss, had at least an equal claim to the protection of the formal tolerance procedures as did respondents in this case, whose claim of injury is far more speculative.

The court of appeals' interpretation of Section 346 is also inconsistent with the Seventh Circuit's interpretation of 21 U.S.C. 346a(b), which deals with the promulgation of regulations applicable to pesticide residues on raw agricultural products and contains the same critical phrase as Section 346. Section 346a(b) provides in pertinent part (emphasis added):

> *The Administrator [of EPA] shall promulgate regulations establishing tolerances* with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, *to the extent necessary to protect the public health.*

In *United States* v. *Goodman,* 486 F.2d 847, 854 (7th Cir. 1973), the court construed this provision to allow EPA the discretion to decide whether to set a tolerance:

> The language of Section 346a(b) provides for promulgation of regulations establishing tolerances "to the extent necessary to protect the public health." EPA has determined that a regulation for DDT in raw fish is not necessary at this time. In fact, they have refrained from promulgating such a regulation because DDT levels in the environment are in a state of flux, a state partially induced by their other control activities concerning DDT.

This interpretation supports the FDA's understanding of the language in Section 346 and clashes sharply with that of the D.C. Circuit in this case.[6]

To be sure, *Boston Farm Center* and *Goodman* did not arise in precisely the same posture as the present case. If there were a significant possibility that such a case might arise in a court of appeals other than the D.C. Circuit, it might be appropriate for this Court to defer review until that occurred. But the likelihood that any circuit other than the D.C. Circuit will confront the legal issue decided below seems remote. Any party seeking to compel the FDA to issue a formal regulation may bring suit in the District of Columbia (see 5 U.S.C. 703), and in view of the decision below such a party is almost certain to make that choice of venue.

3. Unless reversed, the court of appeals' decision will have significant adverse practical consequences. In the first place, it will impose a severe administrative burden on the FDA and require the reallocation of scarce resources from activities of far greater value in protecting public health. As Congress has observed, the formal rulemaking procedures set out in 21 U.S.C. 371 are "cumbersome, time-consuming, and impracticable." S. Rep. 1635, *supra,*

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[6] While the language of Sections 346 and 346a is similar in the respect noted above, the overall scheme for regulating pesticide chemicals in or on agricultural commodities differs significantly from the statutory scheme governing other added, deleterious or poisonous substances. Accordingly, we do not believe that the decision of the court of appeals applies to action levels for pesticides.

at 2; H.R. Rep. 1385, *supra,* at 2.[7] Yet the D.C. Circuit's decision would mandate such proceedings for numerous substances. The FDA currently has 21 informal action levels for eight substances that could be regarded as within the scope of Section 346,[8] and the decision below, at the least, would seem to require that each of these be replaced by a formal tolerance. Moreover, the logic of the court of appeals' decision is not limited to those substances for which an action level has been set but rather extends to all added, unavoidable poisonous or deleterious substances in food.

Once formal tolerances are set, they may hamper the FDA's ability to respond quickly to new scientific findings or improvements in manufacturing processes that make it practicable to reduce the level of adulterants. See 21 C.F.R. 509.6(b)(3). If a formal tolerance is in effect, a food that does not exceed the tolerance is automatically deemed to be safe and not adulterated under Sections 342(a)(2) and 346. In addition, Section 346 provides that

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[7] This is graphically illustrated by the adoption of formal tolerances for polychlorinated biphenyls (PCBs) in paper materials used in packaging foods. In March 1972, the FDA proposed to establish formal tolerances for PCBs in food and paper food-packaging materials. 37 Fed. Reg. 5705. In July 1973, the FDA published a final rule based on the proposal. 38 Fed. Reg. 18096. At the request of several paper industry firms a public hearing was granted. 40 Fed. Reg. 11563 (1973). Subsequently, the FDA's Bureau of Foods and the industry parties reached a proposed settlement agreement, which was submitted for the Commissioner's approval in November 1978. After further proceedings, a revised settlement agreement was announced in the *Federal Register* in August 1983. 48 Fed. Reg. 37020. Thus, the promulgation of a formal tolerance—where there was an objection but no full trial-type hearing—took more than a decade to complete.

[8] FDA action levels to which Section 346 could apply are: aflatoxin, cadmium, crotolaria seeds, mercury, nitrosodimethylamine (NDMA), paralytic shellfish toxin, polybrominated biphenyls (PBBs), and plychlorinated biphenyls (PCBs).

the food may not then be considered to be adulterated within the meaning of Section 342(a)(1)—even if the government could prove in court that the food may be "injurious to health." Thus, if a formal tolerance is issued and it is later discovered that the limit is too high, foods that satisfy the formal tolerance but that may in fact be unsafe according to the latest scientific studies will still be considered safe and unadulterated under the FDCA until the lengthy process of issuing a new, lower tolerance can be completed.[9]

Finally, the reasoning of the court of appeals casts a cloud over the legality of much of the nation's food supply. As previously noted, one of the two bases for the decision below was the court's mistaken belief that unless a formal tolerance has been issued any food containing an added, unavoidable poisonous or deleterious substance must be considered to be adulterated. Since much of the food supply now contains such substances (albeit in safe amounts), the obvious implication of the court's reasoning is that this food is "adulterated" within the meaning of 21 U.S.C. 331 and that persons responsible for growing, processing, or distributing it are subject to injunction (21 U.S.C. 332), seizure of the food (21 U.S.C. 334), or even criminal penalties (21 U.S.C. 333). For those potentially affected, it is cold comfort that the court's pronouncement

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[9] This, too, is illustrated by the FDA's experience with the formal PCB tolerances. Based on newly obtained toxicological data, the FDA in April 1977 proposed to lower the existing tolerance for residues of PCBs in fish, shellfish, and several other classes of food. 42 Fed. Reg. 14487. The final rule was promulgated in 1979. 44 Fed. Reg. 38330. At the request of a fishing industry trade association, a hearing was held in May 1981, and the FDA issued its decision in March 1982. 47 Fed. Reg. 10079. After the agency invited the submission of other relevant materials (*ibid.*), the final decision was issued in May 1984. 49 Fed. Reg. 21514. Accordingly, the entire process of lowering the tolerance for PCBs in fish and shellfish took seven years, although a comparable amendment of an action level probably could have been effected in a relatively brief period.

was dictum and that the government would exercise its enforcement discretion in a fair and reasonable manner. See 21 U.S.C. 336; *Heckler* v. *Chaney,* No. 83-1878 (Mar. 20, 1985). If the court of appeals' decision is allowed to stand, one of two things must happen. Either there must be a cessation of the production and shipment of all foods containing any amount of any added poisonous or deleterious substance, or all segments of the food industry must act in apparent violation of the FDCA until the lengthy process of issuing formal tolerances is completed. We assume that the latter course would be followed in the absence of congressional action, but we do not believe that the agency and the food industry should be compelled to operate under such conditions.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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OCTOBER 1985

APPENDIX A

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 84-5223

(Civil Action No. 80-03110)

COMMUNITY NUTRITION INSTITUTE, ET AL.,
APPELLANTS

v.

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Argued January 25, 1985
Decided March 26, 1985

Before: MIKVA, EDWARDS, and STARR, *Circuit Judges.*

Opinion for the Court filed by *Circuit Judge* STARR.

STARR, *Circuit Judge*: This case presents a challenge to the Food and Drug Administration's regulation of corn adulterated by the presence of aflatoxin. Aflatoxins are by-products of certain common molds that grow on various crops, including corn. The Food and Drug Administration ("FDA" or "agency") permits the shipment of corn containing aflatoxin below an informally adopted "action level." The agency has from time to time granted exemptions to its prescribed action level; moreover, the FDA has permitted blending of adulterated and unadulterated corn to obtain a mixture which the agency believed safe for use as animal feed.

Plaintiffs-appellants, two public interest groups—Community Nutrition Institute and Public Citizen Litigation Group—and an individual consumer (jointly referred to as "CNI"), brought suit in federal district court to require the FDA to adopt, by way of notice-and-comment rulemaking, formal aflatoxin levels or "tolerances," as opposed to informally implemented action levels.[1] Alternatively, CNI argued that, if action levels rather than formally adopted tolerances were permitted, their adoption or amendment and the grant of any exemptions must be treated as rulemakings subject to the procedural requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553 (1982). Finally, CNI argued that the regulations permitting blending of adulterated and unadulterated corn were contrary to law.

The District Court granted summary judgment in favor of FDA on all three issues. We now reverse with respect to the first issue and hold that, under the plain meaning of the statute, the FDA may not proceed by means of action levels rather than tolerances. By virtue of that disposition, the second issue with respect to the procedures to be employed by the agency in adopting action levels is rendered moot. As to the third issue, the blending of adulterated and unadulterated corn, we vacate that portion of the District Court's judgment and remand for further consideration in light of our holding with respect to the FDA's statutory obligation to promulgate regulations setting forth formal tolerances.

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[1] Standing was not contested below or on appeal. It is apparently conceded under the broad grant of standing found in the relevant sections of the Food, Drug and Cosmetics Act and the Administrative Procedure Act. *See* 21 U.S.C. § 371(f)(1) (1982); 5 U.S.C. § 702 (1982). *Compare Block* v. *Community Nutrition Institute*, 104 S. Ct. 2450, 2454-56 (1984) (5 U.S.C. § 702 review is unavailable when the statute relevant to the action precludes review by the class to which plaintiff belongs).

I

Aflatoxins cause liver damage and exhibit carcinogenic properties in animals; evidence also exists suggesting that their ingestion may cause liver cancer in humans. It is thus undisputed that aflatoxin is a "poisonous or deleterious substance" within the meaning of section 402 of the Food, Drug and Cosmetics Act, 21 U.S.C. § 342 (1982) ("the Act"). Furthermore, since aflatoxin is not an inherent constituent of corn, but results from an environmental or agricultural contaminant,[2] it must be considered an "added" poisonous or deleterious substance within the meaning of the statute.[3]

Since aflatoxin is an "added" substance, it comes within the scope of 21 U.S.C. § 342(a)(2)(A), which provides that "[a] food shall be deemed to be adulterated— . . . if it bears or contains any added poisonous or added deleterious substance . . . which is unsafe within the meaning of section 346 of this title. . . ." Section 346 in turn provides:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe . . . ; *but when such substance is so required*

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[2] Weather conditions, insect damage and possibly other factors as well may create conditions that may foster the growth of the molds that produce aflatoxin. *See* Appellee's Brief at 5 n.2.

[3] A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination. . . . An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance.* * * *
21 C.F.R. §§ 509.4(c), (d) (1984).

or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe. . . . While such a regulation is in effect limiting the quantity of such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated. . . . In determining the quantity of such added substance to be tolerated . . . the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided . . . and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

21 U.S.C. § 346 (emphasis added).

Not only is it undisputed that aflatoxin is "poisonous or deleterious" and that it is an "added" substance, but the Secretary also admits facts, *see* Appellee's Brief at 4, sufficient to conclude that the presence of aflatoxin in food may render such consumables injurious to health. Hence, section 342 would, except for the saving grace of section 346, define any aflatoxin-tainted corn to be adulterated, and such corn would therefore be banned from interstate commerce, *see* 21 U.S.C. § 331(a). Nonetheless, since it is also undisputed that aflatoxin is unavoidable, occurring as it does in nature, section 346 may still allow for its interstate transportation. The question before us is what, if any, procedures the Secretary or her delegate, the Commissioner of FDA, is required to follow in invoking the savings provisions of section 346.

The principal point of contention between the parties is over the meaning of that portion of the statutory provision, highlighted in the text above, which reads: "[B]ut

when such substance . . . cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health. . . ." Emphasizing the word "shall," CNI argues that the Secretary is statutorily obligated to issue regulations embodying a tolerance for the substance before the product may lawfully be introduced into interstate commerce. The Commissioner, on the other hand, maintains that this provision merely *authorizes* FDA to issue tolerances but that the agency may, alternatively, elect to proceed by means of informal action levels indicating the levels of contamination below which the FDA will exercise its enforcement discretion, provided under 21 U.S.C. § 336,[4] not to take action. We are thus required to divine the intent of Congress with respect to FDA's authority in this respect under the Act.

II

In questions of statutory construction, our initial inquiry must be, as this court has recently stated, to "determine whether Congress 'has directly spoken to the precise question at issue.'" *General Motors Corp.* v. *Ruckelshaus,* 742 F.2d 1561, 1566 (D.C. Cir. 1984) (*en banc*) (quoting *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 104 S. Ct. 2778, 2781, (1984)). In that process, "reviewing courts . . . must not 'rubber-stamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute.'" *Bureau of Alcohol, Tobacco and Firearms* v.

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[4] "Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336.

Federal Labor Relations Authority, 104 S. Ct. 439, 444 (1983) (quoting *NLRB* v. *Brown*, 380 U.S. 278, 291-92 (1965)). *See also Chevron, supra*, 104 S. Ct. at 2781-82, ("If the intent of Congress is clear . . . the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

After careful review, we find that Congress has spoken on the issue in question and that the intent of Congress is abundantly clear in requiring the formal issuance of tolerances, rather than permitting agency reliance solely on informal action levels. The interpretation accorded the Act by the FDA flies in the teeth of Congress' clear intent and, under long established principles of administrative law, must therefore be rejected.

A

Our analysis begins, of course, by turning to the language of the statute itself. *See, e.g., Consumer Product Safety Comm'n* v. *GTE Sylvania,*, 447 U.S. 102, 108 (1980) ("the starting point for interpreting a statute is the language of the statute itself"); *Reiter* v. *Sonotone Corp.*, 442 U.S. 330, 337 (1979) ("our starting point must be the language employed by Congress"); *Center for Auto Safety* v. *Ruckelshaus*, 747 F.2d 1, 3 (D.C. Cir. 1984) (same, quoting *Reiter*). The presence of the critical word "shall" plainly suggests a directive to the Secretary to establish a tolerance, if a food with an unavoidable poisonous or deleterious substance is to be considered unadulterated. The FDA's response to this common-sense reading is to point to the statutory phrase, "to such extent as [the Secretary] finds necessary for the protection of public health." The FDA contends that this phrase modifies the word "shall," and that the agency's decision to proceed by action levels rather than tolerances properly lies within the FDA's broad discretion. Under this view, the Commissioner may simply conclude that establishing a tolerance is not

necessary for the protection of public health and, so the FDA argues, the agency may thus proceed by informal action levels.

It is, however, clear from the structure of the sentence at issue here that the phrase relied upon by the Secretary simply does not modify the pivotal word "shall." Rather, the qualifying phrase serves an entirely different office; it explains the standard that the Secretary is to employ in setting the tolerance. The Secretary must promulgate regulations embodying tolerances, but the level above which food is taken to be adulterated is to be that which the agency "finds necessary for the protection of public health."

This conclusion is supported by the overall structure of the statutory section in question. Section 346 first provides any poisonous or deleterious substances added to any food are deemed to be unsafe; however, an exemption is also built in to the opening provisions of section 346. Specifically, the statute exempts foods containing *unavoidable* adulterants. But the language does not stop there; the provision then states that the Secretary "shall" promulgate regulations (*i.e.*, set tolerances) limiting the quantity of the substance. Further, the section provides that, when a regulation establishing a tolerance is in effect, such food will not be considered adulterated. Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce.

In arguing, quite correctly, that language must be treated in context, the FDA urges us to look to section 336 of the Act. *See supra* note 4. There, the agency divines a grant of discretion not to establish tolerances yet to allow the shipment of corn below the prescribed action level. The FDA argues that this section thus

allows it to issue action levels standardizing the exercise of prosecutorial discretion.

The language of section 336 does lend modest support to FDA's position: "Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunctive proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. However, the prosecutorial discretion for which the FDA argues here does not appear to be that envisioned by this particular provision of the statute. Section 336, in effect, requires the Secretary to issue a written notice or warning in instances in which the agency decides not to take some form of enforcement action. That section does not, however, allow the shipment of aflatoxin-tainted corn without the establishment of a tolerance. Rather, it clearly vests the agency with discretion to decline to prosecute someone who exceeds the tolerance, even if the tolerance is zero, if the FDA determines that a written notice or warning will be adequate to protect the public interest.

B

The language of the statute clearly requires the issuance of formal regulations or tolerances.[5] While, as both

[5] FDA does not, or could it, argue that adhering to the plain language of the statute would lead to an irrational result or have effects destructive of the policy considerations that informed the enactment of the legislation in the first instance. *Compare, e.g., Commissioner* v. *Brown*, 380 U.S. 563, 571 (1965) (courts have some scope to reject a common or literal meaning " 'where acceptance of that meaning would lead to absurd results . . . or would thwart the obvious purpose of the statute' ") (quoting *Helvering* v. *Hammel*, 311 U.S. 504, 510-11 (1941)). Instead, the agency argues that requiring full-blown notice-and-comment procedures would be highly burdensome and unduly time-consuming for a regulatory

parties invite us to do, we will consider the legislative history, "[a]bsent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." *Consumer Product Safety Commission* v. *GTE Sylvania, Inc., supra,* 447 U.S. at 108. Upon analysis, we find little guidance in the legislative history and certainly not the clear intention necessary to counter the expression of clear language of the statute.

As is usually the case, both sides have emerged from their respective digs into the history of this legislation pointing to historical items supportive of their respective theories. CNI claims support for its position from the fact that, while the Senate version of the bill *authorized* the Secretary to issue tolerances, a subcommittee of the House Interstate and Foreign Commerce Committee changed the language to provide that the Secretary *shall* promulgate tolerances. FDA does not quarrel with this find unearthed by CNI, but asserts that no conclusion of moment should be drawn from the fact of this change. Indeed, as is not infrequently the case in the precincts of legislative history, the subcommittee did not explain, in the committee print, its reasons, if any, for modifying the language in this respect. *See House Committee on Interstate and Foreign Commerce, 75th Cong., 1st Sess., Committee Print No. 3* (August 19, 1937), *reprinted in* 81 Cong. Rec. (Appendix) 2341, 2344 (August 21, 1937).

entity which is plagued with limited resources. We are not unmindful of those concerns, but it is simply not our place to do anything about them. Those concerns, rather, are best addressed within the political branches, not the courts. Our task is to interpret the law. We cannot carry out that function in a principled manner by reading the statute with a perspective driven by the exigencies of agency resources or the lack thereof.

For its part, the FDA observes that, when the full House Commerce Committee reported on the Act, the section in question was described in the following way: "This subsection first prohibits the unnecessary addition of poisons. Where such additions are necessary, the establishment of tolerances is *authorized,* based upon the practical necessities for the use of poisonous substances." *See* H.R. Rep. No. 2139, 75th Cong., 3d Sess. at 6 (1938) (emphasis added). Thus, agency "authority" to issue tolerances, as opposed to a statutory *obligation* to do so, is seen by FDA as having been provided for by the Act.

Where we are left at the end of the day with respect to the House Report that the House Report is, at bottom, consistent with either side's position. To be sure, as FDA emphasizes, the Report does state that the Secretary has *authority* to promulgate regulations, and this formulation indeed suggests a grant of discretionary authority. However, when this portion is read in context—as FDA earnestly urges us to do in parsing the statutory language itself—the Report in pertinent part first observes the existence of a ban on adulterated foods and then goes on to say that tolerances are authorized. The indication is that, without the tolerance, shipment of the food would not be allowed. *See id.* at 2 ("The addition of poisons to foods is prohibited except where such addition is necessary or cannot be avoided; *and in such cases tolerances are provided limiting the amount of added poisons* to the extent necessary to safeguard the public health.") (emphasis added). In a word, while the agency has authority to issue tolerances, the Report does not say that it has authority to allow the shipment of adulterated food without issuing such tolerances.

The language of the earlier Senate Report accompanying S. 5, which was the bill considered by the committee in House Report No. 2139, is infected with the

same ambiguity. It prohibits poisonous or deleterious substances and then authorizes the establishment of tolerances. In contrast to the House bill, however, this earlier Senate bill would have established a Presidentially-appointed committee to advise the Secretary in setting tolerances. That measure also provided that the Committee's recommendation would be the subject of a hearing, after which the regulation could be promulgated. The approval of a majority of the committee was required for any such regulation. *See* S. Rep. No. 646, 74th Cong., 1st Sess. 3 (1935). Since this provision changed before enactment, the Report of course is not entitled to much weight. It does, however, indicate that the Senate had expected a far more elaborate procedure than that argued for here by FDA.

C

Beyond these nooks and crannies of legislative history, the FDA argues that ample case law on the very question before us supports the agency's position. We find, however, that the authorities invoked by FDA are decidedly inapposite. For example, the FDA relies upon *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), as support for its position that the agency may, but is not required to, issue tolerances. That case indeed observes that "[i]n implementing the Act, the FDA either may adopt formal regulations . . . or may litigate alleged violations on a case-by-case basis." *Id.* at 151 (citation omitted) (noting also the discretion granted by section 336). However, *Boston Farm Center* is, in respect of the issue before us, a horse of an entirely different color, namely a suit by the United States to halt distribution of aflatoxin-tainted corn. Boston Farm Center, an enterprise situated not in New England but in Georgia, claimed in defending against an enforcement action that FDA could not halt

distribution without first having issued a tolerance. Since evidence existed that aflatoxin was an adulterant and that at the level there present the tainted corn was unsafe, the court held that the FDA could take action in such an individual case, without establishing a rule for all cases. The agency's authority at issue there was the entirely different one of power to enjoin shipment.

The same is true of *United States* v. *Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980), another authority invoked by the Commissioner. In that case, the district court ruled that the item in question there (swordfish) was safe but also found without merit the defendant's contention that the FDA was required to establish a tolerance. *See id.* at 1153 n.2. Here again, it was the United States taking enforcement action, with the defendant claiming that its product could not be prohibited without the FDA's first establishing a tolerance. And, as in *Boston Farm Center*, the ability of the United States to prohibit shipment of food without having first established a tolerance simply does not, in our view, speak to the agency's refusal to establish a tolerance while permitting shipment.

United States v. *Goodman*, 353 F. Supp. 250 (E.D. Wisc. 1972), *aff'd*, 486 F.2d 847 (7th Cir. 1973), and *aff'd sub nom. U.S.* v. *Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), *cert. denied sub nom. Vita Food Products* v. *U.S.*, 420 U.S. 945 (1975), spoke more directly to this point. As in the two cases already discussed, a defendant-shipper had claimed that the FDA could not proceed against him without first establishing a tolerance. The court stated:

> [A]lthough the provisions of subsection (b) [of section 346a, a similarly worded section for the establishment of tolerances,] would seem, facially, to suggest a duty to promulgate regulations that con-

> tain tolerances, I am persuaded that the total statutory scheme contemplates a judicial obligation to enjoin the distribution of unsafe foods even in the absence of a formally promulgated regulation.

Id. at 251. The court thus recognized the narrowly limited scope of the question it was deciding and entered an injunction against the challenged shipment notwithstanding the absence of established tolerances. The court said nothing as to permission to ship without the establishment of tolerances.

Other cases cited by the FDA likewise involved these familiar refrains by defendants in enforcement proceedings that they could not be enjoined from shipping unadulterated food absent the FDA's prior establishment of tolerances. The courts in those cases also held that case-by-case adjudication was allowable, but they did not speak to the precise issue in contention here. *See United States* v. *General Foods Corp.*, 446 F. Supp. 740, 745 (N.D. N.Y.) (also noting that "Congress has apparently mandated that the F.D.A. establish tolerances for poisonous or deleterious substances which are required or unavoidable in the production of food, such regulations relating to adulteration under [21 U.S.C. § 342(a)(2)], see 21 U.S.C. § 346" but that there was no such requirement under the subsection at issue in that case), *aff'd*, 591 F.2d 1332 (2d Cir. 1978); *Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare*, 236 F.2d 866 (2d Cir. 1956) (defendant could not require tolerance before action taken against it).[6]

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[6] The FDA finds further support for the proposition that "shall" does not mean "required" in *United States* v. *Dotterweich*, 320 U.S. 277 (1943), and *United States* v. *Morgan*, 222 U.S. 274 (1911). However, an examination of the cases shows that they fail to support the FDA's position here. In *Dotterweich*, the defendant invoked section 305 of the Act, which read: "Before any violation of

The State of South Carolina, as *amicus curiae* in support of the FDA, presents a separate argument based upon two Supreme Court cases. In *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914), the Court had held that, under the 1906 version of the Act, the simple existence of a deleterious or poisonous substance did not make a product adulterated. Rather, a requirement existed that the substance must be present in such quantity that it might render the product injurious to health. In *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 161 (1958), the Court held that the rule in *Lexington Mill* still applied to section 402(a)(1) of the 1938 Act, 21 U.S.C. § 342(a)(1). From these two cases, South Carolina concludes that to interpret the law so as to require the existence of tolerances—before

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this chapter is reported by the Administrator to any United States Attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceedings." *See United States* v. *Buffalo Pharmacal Co.*, 131 F.2d 500, 502 n.3 (2d Cir. 1942), *rev'd sub nom. United States* v. *Dotterweich*, 320 U.S. 277 (1943). The Supreme Court "agree[d] with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution." *Dotterweich, supra*, 320 U.S. at 279. Turning to the Court of Appeals opinion in that case, we find the appellate court agreeing with the district court's ruling that "the provision for notice and a hearing was an administrative direction to the Administrator rather than a jurisdictional requirement for criminal proceedings." *Buffalo Pharmacal, supra*, 131 F.2d at 502. The case simply does not stand for the proposition that "shall" can be read as "may." To the contrary, "shall" indicated to a singularly distinguished panel of the Second Circuit (L. Hand, Swan, and Chase, JJ.) nothing less than an "administrative *direction*." The court merely concluded that failure to follow that direction did not result in a loss of criminal jurisdiction. *Morgan*, based on the 1906 version of the Act, similarly held that a provision that "notice shall be given" was not a jurisdictional requirement.

shipment is allowed—would be to bar shipment of food containing *de minimus* or harmless traces of poisonous or deleterious substances in violation of *Lexington Mill*.

However, the 1906 and 1938 Acts differ significantly in this area. While the 1906 Act contained a section similar to section 402(a)(1) of the 1938 Act, 21 U.S.C. § 342(a)(1), it did not contain a section equivalent to section 402(a)(2) of the 1938 Act, 21 U.S.C. § 342(a)(2). *See* 34 Stat. 768, 769-70 (1906). It is the latter provision, 21 U.S.C. § 342(a)(2)(A), that defines as "adulterated" food which is unsafe within the meaning of 21 U.S.C. § 346; *Lexington Mill* and *Flemming* thus do not speak to the issue at hand. Any relevance those cases might have is further diminished by the fact that they likewise involved enforcement actions by the United States against producers or distributors; they do not address the FDA's authority *vel non* to allow shipment of adulterated foods without the establishment of tolerances.

III

Since we have concluded that the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1) or unsafe for purposes of 21 U.S.C. § 342(a)(2)(A), we need not consider the second issue on appeal. Appellants' argument that the establishment of action levels, and the amendment of and grant of exemptions thereto, were rulemakings within the meaning of the APA is rendered moot by our determination as set forth above.

Finally, appellants maintained below that the FDA's approval of blending of aflatoxin-contaminated corn was likewise violative of the Act. The District Court rejected this challenge on the ground that the agency

could properly proceed by action levels and could then grant exemptions to these levels. Inasmuch as the District Court's rationale in this respect was premised upon a statutory interpretation that we are constrained to conclude was in error, we vacate as well that portion of the District Court's judgment and remand for further consideration in light of the duty incumbent on the FDA to promulgate regulations setting forth formal tolerances, as well as appellants' further specific arguments advanced in this respect.

It is so ordered.

APPENDIX B

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 84-5223

COMMUNITY NUTRITION INSTITUTE, ET AL.,
APPELLANTS

v.

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

[Filed May 1, 1985]

ORDER

Before: MIKVA, EDWARDS, and STARR, *Circuit Judges.*

It is ORDERED, by the Court, *sua sponte*, that the Opinion for the Court filed by Circuit Judge Starr on March 26, 1985 be, and hereby is, amended as follows:

Page 2, paragraph 2 of text, lines 2-3, eliminate the words "Litigation Group" so that the second public interest group is identified as "Public Citizen".

Per Curiam
For The Court

GEORGE A. FISHER
Clerk

APPENDIX C

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 84-5223

COMMUNITY NUTRITION INSTITUTE, ET AL.,
AND LAURA A. ROGERS

v.

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

[Filed May 23, 1985]

ORDER

Before: MIKVA, EDWARDS, and STARR, *Circuit Judges.*

Upon consideration of appellee's petition for rehearing, it is

ORDERED, by the Court, that the petition is denied.

Per Curiam
FOR THE COURT

GEORGE A. FISHER
Clerk

BY: /s/ ROBERT A. BONNER
ROBERT A. BONNER
Chief Deputy Clerk

APPENDIX D

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No 84-5223

COMMUNITY NUTRITION INSTITUTE, ET AL.,
AND LAURA A. ROGERS

v.

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

[Filed May 23, 1985]

ORDER

Before: ROBINSON, *Chief Judge,* WRIGHT, TAMM, WALD, MIKVA, EDWARDS, GINSBURG, BORK, SCALIA, and STARR, *Circuit Judges.*

Appellee's suggestion for rehearing *en banc* has been circulated to the full Court and no member has requested the taking of a vote thereon. Upon consideration of the foregoing, it is

ORDERED, by the Court *en banc*, that the suggestion is denied.

Per Curiam
FOR THE COURT

GEORGE A. FISHER
Clerk

BY: /s/ ROBERT A. BONNER
ROBERT A. BONNER
Chief Deputy Clerk

APPENDIX E

United States District Court

FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

MARK NOVITCH, ACTING COMMISSIONER
OF FOOD AND DRUGS, DEFENDANT

[Filed Feb. 14, 1984]

ORDER

Upon consideration of the motion of plaintiffs for summary judgment and the motion of defendant to dismiss or, in the alternative, for summary judgment, the memoranda of law in support and opposition, the argument of counsel, the entire record herein, and consistent with the Memorandum Opinion, it is this 14th day of February, 1984,

ORDERED that the motion of plaintiffs for summary judgment be, and hereby is, denied; and it is further

ORDERED that the motion of defendant to dismiss be, and hereby is, denied; and it is further

ORDERED that the motion of defendant for summary judgment be, and hereby is, granted; and it is further

ORDERED that this case be, and hereby is, dismissed with prejudice.

/s/ NORMA HOLLOWAY JOHNSON
NORMA HOLLOWAY JOHNSON
United States District Judge

United States District Court

FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFF,

v.

MARK NOVITCH, ACTING COMMISSIONER
OF FOOD AND DRUGS, DEFENDANT

[Feb. 17, 1984]

MEMORANDUM OPINION

This case involves the toxic substance aflatoxin which is produced by mold on some agricultural products. Aflatoxin has been shown to be a liver carcinogen in laboratory animals, and studies suggest that it may be associated with primary liver cancer in humans. Plaintiffs, Community Nutritition Institute (CNI), Public Citizen (PC), Linda Bardot, and Laura Rogers, seek declaratory and injunctive relief against the Food and Drug Administration (FDA) and challenge the FDA's method of regulating the interstate shipment of corn adulterated with aflatoxin.

This matter is before the Court on cross-motions for summary judgment and the motion of defendant to dismiss. Upon consideration of these motions, the argument of counsel, and the entire record herein, and for the reasons stated below, the Court grants the motion of defendant for summary judgment.

BACKGROUND

The shipment into interstate commerce of adulterated food is expressly prohibited under section 301 of the Food, Drug and Cosmetic Act (Act), 21 U.S.C. § 331.

Section 402 of the Act defines "adulterated food" as, among other things, food which "bears or contains any poisonous or deleterious substance which may render it injurious to health." 21 U.S.C. § 342 (section 402(a)(1)). To enforce this section and prevent the interstate shipment of food containing poisonous substances which may render the food injurious to health, the FDA sets "action levels." These "actior levels" represent the agency's judgment as to the level of contamination which can be permitted before the FDA is prepared to recommend regulatory action under the Act.* Action levels, according to defendant, are established as "in-house prosecutorial guidelines" to implement the adulteration provisions of the statute. At present, action levels are not subject to notice and comment rulemaking procedures under the Administrative Procedure Act (APA). Rather, upon adoption of an action level for a poisonous and deleterious substance, the FDA publishes a notice in the Federal Register announcing the new action level and the availability of all the relevant data. 42 Fed. Reg. 52817 (Sept. 30, 1977). The notice invites public comment on the action level. *Id.* Since 1969, the action level for aflatoxin in animal feed and human food has been 20 parts per billion (ppb). Any product with more than 20 ppb aflatoxin is subject to regulat ry action by the FDA.

The Act also provides that a food is adulterated if it "bears or contains any added poisonous or added deleterious substance . . . which is unsafe within the meaning of section 406. . . ." 21 U.S.C. § 331 (section 402(a)(2)). Section 406 states that if an added poisonous

* Because all FDA initiated enforcement actions are brought by and in the name of the United States, the FDA must recommend each anticipated action to the Department of Justice. 21 U.S.C. § 337. *See Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 598-99 (1950).

substance is required in the production of the food or if it cannot be avoided by good manufacturing practices:

> [t]he Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a).

This section provides for the establishment of formal tolerance levels which, contrary to action levels, are subject to rulemaking procedures of the APA. No formal tolerance level has been set for corn contaminated with aflatoxin.*

Implementation of the adulteration provisions of the Act is an issue before the Court. In 1974 the FDA considered how it might implement the adulteration provisions of the statute by proposing criteria governing when the agency might establish a formal tolerance or an action level and criteria governing exemptions from regulatory action. *See* Notice of Proposed Rulemaking; Poisonous and Deleterious Substances in Food, 39 Fed. Reg. 42743 (Dec. 6, 1974). In that 1974 notice of proposed rulemaking the FDA also made clear its position that section 406 permits, but does not require, the agency to establish formal tolerances for poisonous substances added to food. 39 Fed. Reg. at 42743, 42744, 42745. Further, the FDA made several other proposals in the 1974 notice that are relevant to this case. First, the FDA proposed the use of informal notice and comment

* Aflatoxin is a by-product of the growth of certain molds on crops and, as such, is an "added" poisonous substance. Further, on some susceptible products like corn, aflatoxin cannot be avoided by good manufacturing practices. Therefore, section 406 is applicable to aflatoxin-contaminated corn.

procedures when setting action levels. Second, the FDA proposed that blending a food containing a poisonous or deleterious substance above the tolerance or action level with another lot of food be prohibited. Third, the FDA proposed that any exemptions from regulatory action for food unlawfully contaminated with a poisonous or deleterious substance be published in the Federal Register with time for public comment "whenever feasible" and "in the event there were not time for public comment, the exemption could be issued as a final determination rather than as a proposal."

A final regulation was not promulgated until September 1977. Although the provisions of the 1974 Notice of Proposed Rulemaking contained a prohibition against blending and recommended the use of informal notice and comment procedures when setting action levels, such were deleted from the final regulation and have never been adopted by the FDA. 42 Fed. Reg. 52814 and 52817. The final regulation retained the proposed criteria governing when the FDA would use formal tolerances and when it would use action levels.* It also retained the proposed provisions governing exemptions from regulatory action and permission to market some products contaminated with a poisonous or deleterious substance.**

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* The provisions of the final regulation governing the use of action levels and formal tolerances are now codified in 21 C.F.R. § 109.6 (covering human food) and § 509.6 (covering animal feed).

** The provisions of the final regulation governing exemptions are codified in 21 C.F.R. § 109.8 (human food) and § 509.8 (animal feed). Section 509.8 provides in pertinent part:

> (a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:
>
> (1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption, and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.
>
> (2) Such determination is published as a notice in the Federal Register and public comment shall be invited on the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

Since the final regulations were adopted, the FDA has, on two occasions granted exemptions from regulatory action pursuant to those regulations. In 1978 the FDA permitted corn containing more than 20 ppb aflatoxin to be 'blended' with less contaminated corn and permitted the final blended product to be shipped in interstate commerce. Notice of the exemption and of the availability of information supporting the FDA's decision to exempt was published in the Federal Register as 21 C.F.R. § 509.8 requires. *See* 43 Fed. Reg. 14122-23 (April 4, 1978). The 1978 exemption applied only to corn harvested in 1977 in the southeastern United States and required the approval of the FDA before the blended product could be shipped in interstate commerce. This exemption expired on January 1, 1979. No firm or individual sought to take advantage of the exemption and none of the plaintiffs submitted comments on the exemption after it was published in the Federal Register.

Again in 1980, the FDA granted a limited exemption to its general prohibition against blending contaminated products. *See* 46 Fed. Reg. 7447-49 (Jan. 23, 1981). This exemption came in response to requests from the states of North Carolina, South Carolina, and Virginia. The exemption was announced in the Federal Register in January 1981 and expired January 1982. The notification in the Federal Register solicited public comment and advised the public of the availability of the relevant information. 46 Fed. Reg. at 7447, 7449. The 1980 ex-

emption applied only to corn harvested in 1980 in the three states that solicited the exemption. Contrary to the 1978 exemption, the FDA announced that in this instance it would not recommend regulatory action against corn containing between 20 ppb and 100 ppb aflatoxin or a blended product of no more than 100 ppb aflatoxin "if, *inter alia*, the corn was used only for feeding mature, nonlactating livestock and mature poultry." 46 Fed. Reg. 7448. In all other cases the 20 ppb action level still applied. A decision by the FDA not to recommend regulatory action was, however, contingent upon state and industry compliance with plans designed to ensure that "corn containing between 20 ppb and 100 ppb aflatoxin was not diverted for uses other than as feed for the animals specified and blending of corn achieved a level of no more than 100 ppb aflatoxin." Defendant's Opposition to Plaintiff's Motion for Summary Judgment at 10.

In a letter dated October 6, 1980, plaintiff CNI urged the FDA to reconsider adopting the 1980 exemption. When plaintiffs were unsuccessful, they filed this action.

CONTENTIONS OF THE PARTIES

Plaintiffs move this Court to grant their motion for summary judgment for the following reasons. (1) Plaintiffs assert that section 406 of the Act requires the FDA to establish formal tolerance levels for aflatoxin in corn products and that the use of informal action levels rather than formal tolerance levels is violative of the Act. (2) If a formal tolerance level is not required, plaintiffs contend that the informal action level for aflatoxin in corn and the exemptions thereto set by the FDA are subject to the rulemaking requirements of the APA and the failure of FDA to hold notice and comment proceedings violates the APA. (3) Plaintiffs further maintain

that the FDA's policy of granting exemptions to its long-standing prohibition against blending contaminated products violates the Act and the FDA's own regulations.

Defendant counters these allegations in its motion to dismiss or, in the alternative, for summary judgment by maintaining that plaintiffs fail to state a claim upon which relief can be granted and that the Court lacks subject matter jurisdiction over this action. According to defendant, the FDA is authorized by section 406 of the Act to establish a formal tolerance for aflatoxin in corn but is not required to do so. Further, defendant asserts that the action levels set by the FDA and their exemptions are statements of policy and are not rules; therefore, they are not subject to the notice and comment procedures of the APA. On the issue of blending contaminated corn, defendant argues that the FDA regulations prohibiting "blending" do not apply to the present case and that plaintiffs challenge to the 1980 and 1978 exemptions is moot. In addition, defendant contends that this Court lacks jurisdiction over the subject matter of the case because plaintiffs failed to exhaust administrative remedies and to participate in the notice and comment period following the 1974 Notice of Proposed Rulemaking.

DISCUSSION

It is a long-standing rule of administrative law that a party must exhaust administrative remedies before seeking judicial review of its complaint. *See, e.g. Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971); *McKart* v. *United States*, 395 U.S. 185, 193 (1969). Courts are admonished to exercise jurisdiction only after the administrative agency involved has had an opportunity to hear the matter, apply its expertise, and develop a factual record of its decision. *McKart*, 395

U.S. at 194. The doctrine of exhaustion is intended to prevent unnecessary interference by the courts into the administrative process. Another purpose behind the doctrine involves the practical notion of judicial efficiency that comes into play if agency consideration of the issues could resolve the dispute and obviate the need for judicial action. *Id.* at 195. However, in instances where efforts to completely exhaust administrative remedies would be an exercise in futility, *Lodge 1858, American Federation of Government Employees* v. *Paine,* 436 F.2d 882, 896 (D.C. Cir. 1970), or where the issue involved is a "pure question of law," *Association of National Advertisers, Inc.* v. *FTC,* 627 F.2d 1151, 1157 (D.C. Cir. 1979), immediate judicial review is available. Defendant maintains that plaintiffs failed to exhaust their administrative remedies by not first presenting their claims to the FDA by petition. The Court finds that plaintiffs need not exhaust the available administrative remedy. First, plaintiffs' claim that section 406 of the Act requires the FDA to establish formal tolerances for corn products contaminated with aflatoxin is a question of law. Whether the Act affirmatively requires the FDA to take certain action is a legal question about which the agency can contribute no particular expertise. *Id.* at 1157. Second, further exhaustion of plaintiffs' challenge to the FDA's policy of not invoking notice and comment rulemaking procedures before setting action levels would not serve the purposes behind the exhaustion doctrine. This challenge does not involve disputed factual issues demanding creation of a better administrative record. *Id.* Further, the FDA has already considered these issues in its 1974 Notice of Proposed Rulemaking and the agency's position on them is clear. *National Resources Defense Council* v. *Train,* 510 F.2d 692, 703 (D.C. Cir. 1974). Finally, plaintiffs challenge the FDA's policy of permitting, in limited instances, the

blending of contaminated corn products. Plaintiffs seek a declaratory judgment from this Court that such a policy is contrary to the Act. Again, this issue was explored and considered in the 1974 Notice of Proposed Rulemaking. To require the FDA to reconsider it would be an exercise in futility. Because none of the issues raised by plaintiffs involve intricate factual determinations, the agency can bring no particular expertise to this case that has not already been expressed in prior agency action. Further exhaustion is not warranted.

Another issue raised by defendant involves the well-settled rule that those who do not participate in rulemaking proceedings before the administrative agency cannot come before the Court complaining about the regulations resulting from those proceedings. *Nader* v. *NRC,* 513 F.2d 1045, 1054-55 (D.C. Cir. 1978). In this case, defendant asserts that plaintiffs should be barred from bringing this action because the acts about which plaintiffs complaint were fully considered in the notice and comment proceedings for the 1974 Notice of Proposed Rulemaking and plaintiffs' complaint was based upon regulations or proposed regulations that arose out of the 1974 Notice of Proposed Rulemaking. While those proposed regulations were open to public comment for several years, plaintiffs did not, at that time, challenge or support any of the proposals. The Court feels compelled, however, to allow plaintiffs complaint to proceed. Mindful of the Supreme Court's view that "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review," this Court will not bar plaintiffs' claim simply because they did not participate in the general Notice of Proposed Rulemaking a decade ago. *Abbott Laboratories* v. *Gardner,* 387 U.S. 136, 141 (1967). Fairness dictates judicial review in this instance.

Defendant's final procedural challenge to plaintiffs' complaint raises a question of mootness. Defendant maintains that plaintiffs' challenge to the grant by the

FDA of exemptions in 1978 and 1980 is moot because those exemptions have expired. Defendant argues that there is no live case or controversy with respect to those exemptions. If plaintiffs were asking this Court to declare those specific exemptions violative of the Act, defendants assertions of mootness would be correct. Rather, plaintiffs here challenge the FDA's authority to grant *any* exemptions without first complying with informal rulemaking procedures. *See* Plaintiffs' Opposition to Defendant's Motion for Summary Judgment at 16. In essence, plaintiffs are challenging the validity of the regulations upon which the FDA relies to grant exemptions. Therefore, the Court finds that the issue is not moot.

Formal Tolerances

Plaintiffs contend that section 406 of the Food, Drug and Cosmetic Act requires the FDA to establish, by formal rulemaking, tolerance levels for aflatoxin in corn. Further, plaintiffs argue that the FDA's use of action levels instead of tolerances in its enforcement of the adulteration provision of the Act is violative of section 406. Section 406 provides that when an added poisonous or deleterious substance is required in the production of a food or cannot be avoided by good manufacturing practices "the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe" for purposes of the adulterated food provision of the statute, section 402(a)(2)(A). Plaintiffs cite the language—"the Secretary *shall* promulgate regulations"—as authority for the proposition that formal tolerances are required. In addition, plaintiffs assert that legislative history supports their interpretation because Congress considered, but ultimately rejected, language stating that "the Secretary is authorized to promulgate regulations."

Plaintiffs' claim is without merit. The language of section 406 states that the Secretary shall promulgate regulations "to such extent as he finds necessary for the protection of public health." The FDA has interpreted this provision of the Act to mean that, in its discretion, it may decide that a tolerance is not necessary to protect the public health and therefore can decline to establish one. This interpretation has been codified in the agency's regulations at 21 C.F.R. § 509.6.

The Court recognizes that the FDA's interpretation of its own statute is entitled to "substantial deference." *United States* v. *Rutherford*, 442 U.S. 544, 553 (1979). Such deference is particularly appropriate here, where courts have consistently agreed with this interpretation. The Fifth Circuit in *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149, 151 (5th Cir. 1979), stated that "[i]n implementing the Act, the FDA either may adopt formal regulations, 21 U.S.C. § 346 [section 406], or may litigate alleged violations on a case-by-case basis [pursuant to 21 U.S.C. § 342(a)(1) (section 402(a)(1)]." *Boston Farm Center*, like the instant case, involved aflatoxin in corn. Similarly, a district court in Florida noted that there was no merit to plaintiff's contention that section 406 required the FDA to establish a tolerance for mercury in swordfish. *United States* v. *Anderson Seafoods*, 447 F. Supp. 1151, 1153 n.2 (N.D. Fla. 1978), *aff'd*, 662 F.2d 157 (5th Cir. 1980).

Mindful of the principle that "the construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong," *Red Lion Broadcasting Co.* v. *FCC*, 395 U.S. 367, 381 (1969), the Court finds that the FDA's interpretation is reasonable and that section 406 confers discre-

tionary, not mandatory, authority on the agency to establish tolerances.*

Informal Action Levels and Exemptions

To guide in the enforcement of section 402(a)(1) of the statute which deems a food to be adulterated "if it bears or contains any poisonous or delet[illegible]ious substance which may render it injurious to heal[illegible] the FDA sets action levels. These action levels are s[illegible]ursuant to the FDA's prosecutorial discretion to [illegible]rosecute or litigate "minor violations" of th[illegible]ct § 336 (Section 306). Plaintiffs maint[illegible]e FDA s action level for aflatoxin in corn, and the 1978 and 1980 exceptions to it, are subject to the rulemaking requirements of the APA and the failure of FDA to hold such notice and comment proceedings is violative of the APA.

Plaintiffs' contentions ignore the difference between substantive rules and general statements of policy. Unlike substantive rules, general statements of policy are not subject to informal rulemaking under the APA. 5 U.S.C. § 553(b)(A). In *Pacific Gas & Electric Co.* v. *FPC*. 506 F.2d 33, 38 (D.C. Cir. 1974), this Circuit noted that the "critical distinction between a substantive rule and a general statement of policy is the different practical effect that these two types of pronouncements have in subsequent administrative proceedings." A substantive rule establishes a standard of conduct which has the force of law, whereas a general statement of policy does not establish a "binding norm." *Id.*

Action levels are "in-house guidelines" that guide the FDA in its prosecutorial discretion in bringing about the enforcement of the Act. *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149, 151 (5th Cir. 1979). While a

* Plaintiffs are still free to petition the agency under 21 C.F.R. § 10.25 and request that a formal tolerance be set.

court should accord deference to the FDA's action levels, they are not binding on the courts. *Id.* Moreover, action levels only represent the point at which the FDA *may* recommend regulatory action. Action levels are not substantive rules but general statements of policy. Accordingly, they are not subject to informal rulemaking procedures.

Exemptions to the 20 ppb action level for aflatoxin in corn were issued in 1978 and 1980 pursuant to FDA regulations 21 C.F.R. § 509.8. Plaintiffs argue that these exemptions are also subject to informal rulemaking procedures under the APA. Under section 509.8 the FDA must publish in the Federal Register a notice advising the public of the FDA's final action but is not required to publish a notice of proposed exemptions open to public comment. In essence, plaintiffs' complaint challenges the validity of section 509.8.*

As the Court previously noted, an agency's characterization of its own proceedings is entitled to some "weight" by the Court and "that characterization may in turn have relevance in determining the applicability of the APA rulemaking requirements." *In re FTC Corporate Patterns Report Litigation*, 432 F. Supp. 291, 304 (D.D.C. 1977), *aff'd*, 595 F.2d 685 (D.C. Cir.), *cert. denied*, 439 U.S. 958 (1978). The Court has already determined that the agency's characterization of action levels as general statements of policy and not substantive rules, is a reasonable one. General statements of policy leave the agency free to exercise its informed discretion and such statements do not impose a binding obligation on the agency. *American Bus Association* v. *United States*, 627 F.2d 525, 529 (D.C. Cir. 1980). Therefore, by granting exemptions to action levels the

* Plaintiffs must challenge the validity of the *regulations* allowing exemptions without notice and comment rulemaking. Any challenge to the specific exemptions themselves would be moot.

FDA is simply acting on its discretionary authority not to follow its own "in-house guidelines." A change in a prosecutorial guideline or general statement of policy, which is itself not subject to notice-and-comment, cannot suddenly become subject to the notice-and-comment requirement.

Finally, plaintiffs assert that the FDA's approval of the blending of aflatoxin-contaminated corn is contrary to the Act. This assertion does not square with the Court's finding that action levels are general statements of policy. The FDA retains discretion as to when to recommend an enforcement action and exemptions to action levels are within that discretion. The factors which the FDA evaluates in determining whether an exemption from an action level is appropriate are set forth in the FDA's regulations. 21 C.F.R. § 509.8. Exemptions to action levels, whether through blending or otherwise, are clearly permitted under the FDA's regulations, provided the Commissioner makes the determination that "based upon all available scientific evidence, . . . the food is safe for consumption, and . . . that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply." The Court finds no reason to disturb the agency's characterization of its own statute and accords deference to the agency's regulations.

Accordingly, the Court grants the motion of defendant for summary judgment and denies the motion of plaintiffs. An Order consistent with this Opinion has been entered.

/s/ NORMA HOLLOWAY JOHNSON
NORMA HOLLOWAY JOHNSON
United States District Judge

DATED: February 17, 1984

APPENDIX F

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 84-5223

COMMUNITY NUTRITION INSTITUTE, ET AL.,
APPELLANTS

v.

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

[Filed Mar. 26, 1985]

JUDGEMENT

Before: MIKVA, EDWARDS, and STARR, *Circuit Judges.*

This cause came on to be heard on the record on appeal from the United States District Court for the District of Columbia, and was argued by counsel. On consideration thereof, it is

ORDERED and ADJUDGED, by this Court, that the judgment of the District Court appealed from in this cause is hereby reversed in part, and vacated in part, and this case is remanded for further consideration, all in accordance with the Opinion for the Court filed herein this date.

Per Curiam
For The Court
GEORGE A. FISHER
Clerk

Date: March 26, 1985
Opinion for the Court filed by Circuit Judge Starr.

APPENDIX G

STATUTORY AND REGULATORY PROVISIONS INVOLVED

1. Section 402(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a), provides:

A food shall be deemed to be adulterated—

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw

agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

2. Section 406 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346, provides:

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) (A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health,

and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

3. Section 701(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(e), provides:

> (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

> (2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.
>
> (3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

4. 21 C.F.R. 509.6(b)-(c) provides:

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

Supreme Court, U.S.
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CLERK

No. 85-664

IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

May the Food and Drug Administration set levels for unavoidable food contaminants without providing any opportunity for public participation, where the Food, Drug and Cosmetic Act, 21 U.S.C. § 346, states that the FDA "shall promulgate regulations limiting the quantity" of such contaminants through a formal rulemaking proceeding?

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No. 85-664

FRANK YOUNG, COMMISSIONER, FOOD AND DRUG ADMINISTRATION,

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COMMUNITY NUTRITION INSTITUTE, *et al.*,

Respondents.

BRIEF FOR RESPONDENTS IN OPPOSITION

STATEMENT

This action challenges the method used by the Food and Drug Administration ("FDA") to regulate aflatoxins. Aflatoxins are a group of chemically related substances produced by molds which grow on corn and other agricultural products. They cause cancer in laboratory animals and are suspected of causing human liver cancer. App. 3a.[1] According to the National Academy of Sciences, aflatoxin B, the prevalent member of the strain, is "the most potent carcinogen known in laboratory animals."[2]

Although section 406 of the Federal Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. § 346, establishes a method for setting tolerances for aflatoxins and other unavoidable substances

[1] "App.__" refers to the Appendix to the Petition for a Writ of Certiorari; "Pet. at__" refers to the body of the petition.

[2] National Academy of Sciences, *Food Safety Policy, Scientific and Societal Considerations* (March 1979), p. 3—49.

which are unsafe, the FDA has issued only one tolerance in the 47 years since Congress adopted that provision. In every other instance, the agency has regulated these substances through informal action levels, which it sets and amends unilaterally, without any opportunity for public input, and without creating an administrative record that provides evidentiary support for its decision.

A. *Statutory Framework*

Section 402 of the FDC Act, 21 U.S.C. § 342, defines "adulterated" as that term pertains to food, and section 301(a), 21 U.S.C. § 331(a), prohibits the shipment of adulterated food in interstate commerce. Sections 402 and 406, 21 U.S.C. §§ 342, 346, divide substances which can cause food to be adulterated into several classifications and impose different standards on each category. The first category is poisonous or deleterious substances which are inherent in the food. Under section 342(a)(1), a food containing such a substance is adulterated only if the substance would "ordinarily render [the food] injurious to health."

A second category is poisonous or deleterious substances which are added to food, and these substances are regulated both by section 342(a)(1) and by section 346. Section 342(a)(1) sets a single standard for all added substances and declares that a food containing an added poisonous or deleterious substance is adulterated if the substance "may render [the food] injurious to health." This is a more rigorous standard than the "ordinarily" render injurious standard applicable to inherent substances.

However, in section 346, Congress subdivided added poisonous or deleterious substances into two additional categories. If the substance is intentionally added, the first sentence of section 346 declares that food containing it is "unsafe", without any requirement that there be a showing that it "may be injurious to health", and under section 342(a)(2) additives which are unsafe within section 346 are adulterated. In 1938, this provision covered pesticides, food additives, and color additives, although today these substances are largely regulated by separate licensing provisions in the FDC Act. *See* 21 U.S.C. §§ 346a, 348, 376.

Congress adopted a middle level standard for the second category under section 346—unavoidable additives, such as aflatoxin, mercury in fish, and pesticides which have been banned but still contaminate the soil. This provision represents a balance between the goal of eliminating poisonous and deleterious substances from food, and the recognition that some such substances are unavoidable. To implement this standard, in the first clause of section 346, Congress created an exception to the flat ban on added poisonous and deleterious substances, which applies if the substance is "unavoidable." However, in the statutory language which is the subject of this lawsuit, Congress provided that, for unavoidable contaminants:

> *the Secretary* [of Health and Human Services] *shall promulgate regulations* limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of [section 342(a)(2)].

21 U.S.C. § 346 (emphasis supplied). Thus, under this provision, a food is adulterated under section 342(a)(2) if it contains an avoidable, added poisonous or deleterious substance and no tolerance has been issued, or if the amount of the substance exceeds the established tolerance. Section 701(e) of the statute, 21 U.S.C. § 371(e), prescribes the method for setting tolerances: the FDA must use formal rulemaking, providing interested persons notice, an opportunity to comment, and an evidentiary hearing to resolve any material factual issues which are raised by formal objections.

B. *Regulation of Aflatoxin*

Although section 346 uses the word "shall" to describe the Secretary's obligation to promulgate regulations, the FDA has never issued a regulation establishing the limits of aflatoxin in food.[3] Instead, in 1965, the FDA established an "action level" of

[3] The Secretary has delegated virtually all her duties under the FDC Act to the Commissioner of the Food and Drug Administration. 21 C.F.R. § 5.10(a)(1985).

30 parts per billion ("ppb") for aflatoxin, which was the lowest level of contamination which could be detected under technology existing at that time. 39 Fed. Reg. 42748, 42749 (Dec. 6, 1974). In 1969, the agency reduced the action level to 20 ppb, where it has remained ever since. *Id.*

The term "action level" appears in neither the FDC Act nor the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551, *et seq.* Instead, action levels are a method of regulation created solely by the FDA. The agency does not issue the action levels for aflatoxin and other unavoidable contaminants as regulations, nor does it publish proposed action levels for comment in the Federal Register. Instead, it simply announces new action levels once they are final. Moreover, since 1938, with one exception, the agency has used action levels rather than the procedures prescribed by the sections 346 and 371(e) to regulate unavoidable, added substances which it has determined cause food to be adulterated.

Action levels were initially publicized through press releases or other announcements, and it was not until 1977 that the agency published an administrative manual containing all existing action levels and indicated that any future action levels would be published in final form in the Federal Register, with a notice inviting public comment. 21 C.F.R. § 109.4(b)(2). However, the FDA does not even assume an obligation to respond to public comments, and it reserves the right to change its action levels at any time, also without allowing the public an opportunity to participate. *Id.*

The regulation of aflatoxin provides an example of how the FDA implements this regulation. In 1978, the FDA deviated from its longstanding prohibition against "blending" contaminated foods, by allowing corn containing aflatoxin at levels greater than 20 ppb to be blended with less contaminated corn, in order to obtain a mixture under the 20 ppb limit. The decision was issued in a January 31, 1978 letter to a private firm and was not published in the Federal Register until April 4, 1978. 43 Fed. Reg. 14122.

In the fall of 1980, the FDA again permitted blending of corn containing aflatoxin above the action level, and again it waited

several months to publish this decision. *See* 46 Fed. Reg. 7447 (Jan. 23, 1981). In response to this announcement, respondents filed the instant lawsuit, challenging both the agency's use of action levels and its policy of permitting blending. In 1983, while the case was pending in district court, the agency once again announced that it had decided to permit blending of corn contaminated with aflatoxin. 48 Fed. Reg. 53175 (Nov. 25, 1983). Pursuant to the FDA's regulations, 21 C.F.R. § 109.4(b)(2), respondents submitted objections to the final decision on December 16, 1983, but the agency never responded.

Although the FDA issues action levels without complying with the formal rulemaking requirements of the FDC Act or the notice and comment requirements of the APA, it treats action levels as though they had the same force as regulations. Thus, for purposes of enforcing the FDC Act's prohibition on adulterated food, the FDA prosecutes persons who ship corn with aflatoxin above the 20 ppb action level, and, more importantly, it also explicitly permits the shipment of corn containing less than 20 ppb aflatoxin. For these reasons, an action level is not simply the equivalent of a decision not to prosecute a manufacturer for a single violation of the FDC Act. Instead, it represents a binding commitment that the agency will permit the sale of products containing contaminants below the action level.

C. *Proceedings Below*

Respondents are two consumer organizations and an individual consumer. Their complaint raised two issues in addition to the claim that the FDA is required to use sections 346 and 371(e) of the FDC Act to set limits for unavoidable contaminants. Thus, respondents alleged that, even if section 346 does not require the FDA to issue tolerances, action levels are "rules" within section 2(c) of the APA, 5 U.S.C. § 551(4), because they are binding on the FDA and have a future effect on the agency and the public. Therefore, at a minimum, the FDA is required to publish action levels as proposed rules and provide an opportunity for public comment. 5 U.S.C. §§ 551(5), 553. *See, e.g., American Bus Ass'n v. United States,* 627 F.2d 525, 529 (D.C. Cir. 1980)("[i]f it appears that a so-called policy statement is in purpose or likely effect one

that narrowly limits administrative discretion, it will be taken for what it is—a binding rule of substantive law" to which the rulemaking provisions of the APA apply, *quoting Guardian Federal Savings & Loan Ass'n v. Federal Savings & Loan Insurance Corp.*, 589 F.2d 658, 666-67 (D.C. Cir. 1978)); *Nader v. Civil Aeronautics Board*, 657 F.2d 453, 456 (D.C. Cir. 1981) ("mandatory language, which narrowly circumscribes the Board's discretion to suspend air fares. . . plainly constitutes a substantive rule"). Respondents' third claim was that the FDA's policy of permitting blending of corn contaminated with aflatoxin violates the FDC Act and the agency's own regulations. *See* pp. 4-5, *supra.*

The district court rejected all three arguments, but the court of appeals reversed the lower court's ruling on the section 346 claim. In a unanimous opinion by Judge Starr, the court held that "the intent of Congress is abundantly clear in requiring the formal issuance of tolerances, rather than permitting agency reliance solely on informal action levels." App. 6a. In doing so, the court gave great weight to the language in the statute: the "presence of the critical word 'shall' plainly suggests a directive to the Secretary to establish a tolerance." *Id.* The FDA had argued that the phrase in the statute "to such extent as [the Secretary] finds necessary for the protection of the public health" qualifies the word "shall" and makes the use of formal tolerances optional. The court rejected that argument on the ground that it is "clear from the structure of the sentence at issue here" that the phrase "simply does not modify the pivotal word 'shall.'" *Id.* at 7a.

Finally, the court held that none of the cases cited by the FDA supported a different result. It found that they all involved the agency's power to enjoin the shipment of adulterated products rather than whether the agency may grant "permission to ship without the establishment of tolerances." *Id.* at 13a. In summary, the court held that "[t]he interpretation accorded the Act by the FDA flies in the teeth of Congress' clear intent and, under long established principles of administrative law, must therefore be rejected." *Id.* at 6a. Since the court concluded that the FDA is required to issue tolerances under section 346, it did not reach respondents' claim that the FDA had also violated the notice and

comment requirements of the APA. *Id.* at 15a. It remanded the blending issue to the district court for consideration in light of its decision. *Id.* at 15a-16a.

Petitioner subsequently filed a petition for rehearing, with a suggestion that the court hear the case *en banc.* The panel denied the petition, and the court denied the suggestion, with a notation that no member had requested a vote on whether the case should be heard by the full court. *Id.* at 18a, 19a.

REASONS FOR DENYING THE PETITION

There is no dispute about the fact that aflatoxin is a poisonous or deleterious substance which is "added" to corn within the meaning of sections 342 and 346 of the FDC Act. Therefore, the only legal issue raised by the petition is whether the FDA may issue informal action levels to permit the sale of corn containing aflatoxin, instead of using the formal tolerance procedures provided in sections 346 and 371(e).

As we demonstrate below, none of the grounds advanced by the FDA justifies granting the petition. First, the court of appeals correctly relied on the language of the statute, and the court correctly held that section 346 directs the FDA to establish tolerances for unavoidable contaminants. Second, the cases from other circuits relied on by petitioner raise the distinctly separate issue of whether the FDA may prosecute manufacturers whose products exceed an action level, even though the agency has not issued a tolerance pursuant to section 346. Since none of those cases involved the opposite side of the coin—the issue of whether the FDA may use action levels to sanction products containing the contaminant—there is no conflict in the circuits which justifies review by this Court.

Finally, the case does not raise an issue of sufficient importance to justify consideration by this Court. As the FDA points out (Pet. at 16), there are only eight substances which have action levels, and there is no support in the record for the agency's claim (*id.* at 7) that it would take "years, if not decades" to issue regulations setting tolerances under section 346. Moreover, the hearing requirements applicable to formal tolerances are similar to the

right to a hearing which Congress has granted to manufacturers of drugs, food additives, and other products regulated by the FDC Act. In light of the policies of both the FDC Act and the APA, the agency's current practice of regulating unavoidable contaminants without any public participation is simply unacceptable, and therefore the decision of the court of appeals enjoining it from continuing this practice should be allowed to stand.

1. The FDA admits that the interpretation of section 346 adopted by the court of appeals is "entirely rational and plausible" (Pet. at 8). Indeed, the lower court's interpretation is the most natural and direct reading of the statute. Thus, section 346 declares that, if an added substance is unavoidable:

> the Secretary *shall* promulgate regulations limiting the quantity therein or thereon *to such extent as he finds necessary for the protection of public health*

(emphasis supplied). The FDA argues that the second italicized portion of the quotation modifies the word "shall", and therefore that section 346 merely authorizes the Secretary to issue tolerances, if he chooses to do so. The flaw in this argument is that it has no support in the structure of the sentence. If Congress had intended the qualifying language to modify "shall", it would have placed the qualification directly after that word. By placing that phrase where it did, Congress indicated that it intended the words "to the extent . . . necessary for the protection of public health" to provide the measure of protection to be used by the FDA in establishing the appropriate tolerance level. Thus, the word "shall" directs the FDA to issue regulations, section 371(e) directs it to use formal rulemaking procedures, and the second italicized clause states that the levels chosen must be those "necessary for the protection of public health."

Second, under the FDA's construction, the statute would have had precisely the same meaning if Congress had used the phrase "is authorized to" in place of the word "shall." In fact, S. 5, the bill adopted by the Senate, used that phrase. S. 5, 75th Cong., 1st Sess. § 15(a) (1937). However, several of the bills which had previously been introduced in the House of Representatives used

"shall" to describe the FDA's duty under the tolerance-setting section. *See* H.R. 6110, 73rd Cong., 1st Sess. § 11(a) (1933); H.R. 8316, 73rd Cong., 2d Sess. § 10(a) (1934). Thus, in considering the Senate bill, the House Committee on Interstate and Foreign Commerce could have adopted either of two very different alternatives. The House committee chose "shall", and therefore it amended the Senate bill to state that the Secretary "shall promulgate regulations" limiting the quantity of unavoidable contaminants. House Committee on Interstate and Foreign Commerce, 75th Cong., 1st Sess., S.5 § 406(a) (Confidential Committee Print No. 2, 1937). This language was ultimately enacted, without change, as section 346 of the FDC Act, and in section 371(e) Congress also required the FDA to adhere to the formal rulemaking requirements when it issued those regulations. This legislative history demonstrates that Congress explicitly drafted the FDC Act to *require* the FDA to limit the amount of unavoidable contaminants in food through regulations adopted pursuant to section 371(e).

For the first time in this litigation, the FDA's petition argues that respondents' interpretation of the Act makes the portion of section 342(a)(1) applicable to added substances superfluous. Pet. at 9. However, this simply is not so, since even if section 346 is mandatory, section 342(a)(1) will continue to apply to poisonous or deleterious additives for which the FDA has not yet issued a tolerance. Thus, on the day the new statute became effective, the FDA did not have tolerances in place. Similarly, in subsequent years, poisonous or deleterious added substances have been identified, which, even under respondents' construction of the statute, cannot be regulated through tolerances until sufficient time has elapsed for the agency to comply with the procedures in section 371(e). For this reason, in section 342(a)(1) of the Act, Congress retained the portion of the Food and Drugs Act of 1906 applicable to added substances, even though in section 346 it directed the agency to issue tolerances for those substances.[4]

[4] The 1906 Act used language which is almost identical to the first clause of section 342(a)(1). It defined food as adulterated if "it contain[s] any added poisonous or other added deleterious ingredient which may render such article injurious to health." 1906 Federal Food and Drugs Act § 7, 34 Stat. 768 (repealed by 21 U.S.C. § 392).

Thus, under respondents' construction of the statute, the portion of section 342(a)(1) which applies to added substances is not superfluous because it may be used whenever a new, added contaminant is discovered.

In fact, it is the FDA's construction of the statute that would make section 346 superfluous. According to the petitioner, the sole purpose of section 346 is to authorize the agency to issue regulations which formalize its action levels. However, even without section 346, the agency would have this authority, since section 701(a) of the Act authorizes it to "promulgate regulations for the efficient enforcement of [the] Act." 21 U.S.C. 371(a). Therefore, under petitioner's own standards of statutory construction, in order to avoid redundancy with section 371(a), section 346 should be construed as requiring the FDA to issue formal tolerances for added poisonous or deleterious substances which are unavoidable.

The pesticide amendments of 1954 also provide no support for the FDA's construction of section 346. As the FDA points out, Congress removed pesticides from the coverage of section 346, and enacted a new provision, 21 U.S.C. § 346a, which establishes somewhat less formal procedures for setting tolerances for pesticide residues in raw agricultural products. These procedures actually support respondents' construction of section 346 in two respects. First, the enactment of the 1954 law suggests that Congress had concluded that the FDA did not then have the authority to use less formal procedures, such as action levels, to regulate pesticides. Second, Congress did not amend section 346, but instead retained that section and the procedures applicable under section 371(e) for substances other than pesticides. Thus, the only reasonable conclusion to draw from the pesticide amendments is that Congress intended the requirements of 346 to continue to apply to all added substances, except pesticides, which would be covered by the less formal procedures in the new law.[5]

[5] This is further demonstrated by testimony given on behalf of the National Canners Association, which appears immediately after the letter quoted in the Petition (*see* Pet. at 11 n.5.):

Congressman O'Hara: This has nothing to do with—this proposed legislation has nothing in the way of an effect upon section 406 [21 U.S.C. § 346] of the present law. This is true, is it not?

Mr. Austern [on behalf of the National Canners Association]: That is true.

Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce, 83d Cong., 2d Sess. 32 (1954). Similarly the FDA's argument that Congress in 1954 concurred with the agency's construction of section 346 is rebutted by the Report of the House Committee on Interstate and Foreign Commerce which noted that "[t]here are no provisions for such exemptions or temporary tolerances in the present law." H.R. Rep. No. 1385, 83d Cong., 2d Sess. 6 (1954).

Having agreed that the court of appeals' interpretation of section 346 is as plausible as the agency's (Pet. at 8), the FDA is left to argue that the court did not accord proper deference to its interpretation of the statute. However, the deference ordinarily accorded an agency's construction of a statute should be tempered where, as is the case here, its construction would lessen the burdens which would otherwise be placed upon it. Just as courts have generally not deferred to agencies in interpreting the procedural requirements of the APA, the FDA's interpretation of section 346 should be given little, if any, deference. In any event, the court of appeals correctly held in this case that the FDA's construction of section 346 is inconsistent with the plain meaning of the statute, and thus the degree of deference accorded is immaterial.

2. Contrary to petitioner's assertions, there is no division among the courts of appeals regarding the correct interpretation of section 346. In *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), the court held that the FDA may use its authority under section 342(a)(1) to initiate enforcement proceedings to enjoin the shipment of corn containing aflatoxin in excess of the agency's 20 ppb action level. In ruling for the FDA, the Fifth Circuit stated that "the FDA either may adopt formal regulations, 21 U.S.C. § 346, or may litigate the alleged violations on a case-by-case basis." *Id.* at 151. Relying on this statement, the FDA argues that *Boston Farm Center* is inconsistent with the D.C. Circuit's decision in the instant case. Pet. at 13.

However, the Fifth Circuit was not presented with the question of whether the FDC Act requires the FDA to use formal rulemak-

ing, instead of action levels, in establishing permissible levels of unavoidable contaminants such as aflatoxin. It only held that the statute prohibits unavoidable contaminants, even where the agency has not established a tolerance, and that the agency may enforce the statutory requirements on a case-by-case basis under section 342(a)(1). The court did not decide the issue in this case, which is whether the FDA may *exempt* contaminants below a specified level without complying with the requirements of sections 346 and 371(e) of the FDC Act.

United States v. Goodman, 486 F.2d 847 (7th Cir. 1973), is distinguishable for the same reason. The court held that the Environmental Protection Agency could prohibit the distribution of fish with *any* DDT residue. Therefore, the defendants were not "harmed" where the agency had declined to issue a formal tolerance but had adopted an action level which gave "them the opportunity to continue to operate if they can distribute fish with 5 or less parts per million of DDT residue." *Id.* at 855. Thus, there is no conflict between the D.C. Circuit's opinion in this case and the decision of any other circuit.

3. The FDA has overstated the adverse implications of the lower court's decision. If the decision stands, the status of foods with respect to section 346 will be precisely the same as it was when the FDC Act became effective. The FDA will be obligated to issue tolerances for substances covered by section 346, but, in the meantime, it may regulate those substances under sections 342(a)(1) and 342(a)(2). Thus, there is no merit to the agency's argument (Pet. at 16) that its ability to regulate unavoidable contaminants will somehow be hampered if it is required to promulgate formal tolerances.

This same practical result has been reached by courts in construing other parts of section 342 as well. Thus, in interpreting section 342(a)(3), which prohibits "filthy, putrid, or decomposed substance[s]"in food, the Fifth Circuit has recognized that this section "sets a standard that if strictly enforced, would ban all processed food from interstate commerce" because a "scientist with a microscope" could find such a substance "in almost any canned food we eat." *United States v. 484 Bags, More or Less,* 423

F.2d 839, 841 (1970), *quoting United States v. 1500 Cases, Etc.,* 236 F.2d 208, 210-11 (7th Cir. 1956). Nevertheless, "the majority, in fact almost unanimous, rule is that the Act confers the power to exclude from commerce all food products which contain in any degree filthy, putrid or decomposed substances", although such "harsh consequences. . . are tempered by discretion given the Secretary." 423 F.2d at 839 (citations omitted). Any "harsh consequences" of the court of appeals' decision here could be tempered in the same manner.

There is also no support for the argument that the process of establishing tolerances under section 346 will impose a severe administrative burden on the agency. As the FDA points out (Pet. at 16), the agency has action levels for only eight substances which are covered by section 346. Moreover, in many respects, the procedures required by sections 346 and 371(e) are similar to the notice and comment procedures mandated by the APA. The only significant difference is that section 371(e) requires the agency to provide an opportunity for an evidentiary hearing where there are disputed issues of material fact.

In comparable circumstances, the FDC Act already provides for a hearing on decisions pertaining to prescription drugs, food additives, and a variety of other products regulated by the agency. 21 U.S.C. §§ 348(f), 355(e), 376(d).[6] Even though thousands of products fall under the jurisdiction of these provisions, the hearing requirement has not paralyzed the FDA because in most cases the agency denies the application for a hearing and issues a summary decision, a procedure which was upheld by this Court in *Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620-22 (1973). Therefore, it is incorrect to assume that the court of appeals' decision would require the FDA to hold hearings even for all of the eight added substances for which it currently has action levels.

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[6] *See* Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act,* 77 Mich.L.Rev. 171, 208 (1978) ("[t]he statutorily prescribed process for approving or withdrawing approval of a food additive is as complex as that required for the establishment of tolerances under section 406 [21 U.S.C. § 346]").

Although it has no statutory foundation, as a policy matter the agency's argument that action levels are temporary measures might carry weight if it were correct in claiming that they are "used when changes in the capabilities of good manufacturing practices are expected or when the results of ongoing studies might provide significant new data or other data that might render a tolerance obsolete." Pet. at 5; *see also* Pet. at 16. Although this is an accurate description of the criteria contained in the agency's regulations and policy statements,[7] the case of aflatoxin graphically illustrates that the agency has never followed this policy. Thus, the action level for aflatoxin has been constant since 1969, *see* p. 4, *supra*, and there are no ongoing technological changes or uncertainties about scientific data which justify a temporary standard. The fact that the agency has issued only one tolerance in 47 years demonstrates beyond any reasonable dispute that it views action levels as a permanent substitute for tolerances under section 346.

The FDA correctly points out that, like any regulation or licensing decision, a formal tolerance could not be revoked or amended as easily as an informal action level. However, this same argument would lead to the conclusion that formal procedures need not be used to license new drugs and food additives, or other products regulated by similar provisions of the FDC Act. Whatever the merits of that argument, it is plainly not the method which Congress chose to regulate unavoidable contaminants, and therefore it does not support the agency's claim that Congress intended to give it the flexibility to regulate section 346 substances without issuing regulations.

In any event, the FDA totally ignores the benefits of using regulations. Under its current practice, it must prove that corn contaminated with aflatoxin above 20 ppb is unsafe each time that it brings a lawsuit for violation of an action level. *See, e.g., United States v. Boston Farm Center, Inc., supra.* On the other hand, if it had issued a formal tolerance, it would have to show

[7] 21 C.F.R. § 109.6(b)-(c); *see also* 42 Fed Reg. 53814, 52817 col. 1-3 (September 30, 1977); 39 Fed. Reg. 42743, 42745 col. 3 (December 6, 1974).

only that the level of aflatoxin exceeded the tolerance; any challenge to the tolerance would have to be made directly, and not as a defense to a court action. Thus, while the agency would have to use resources in setting the tolerance, it would save resources when prosecuting companies which have violated its regulations. Moreover, by permitting public participation, the agency would make more informed decisions regarding the regulation of substances which are poisonous or deleterious when added to foods.

In summary, while there are policy arguments which can be made on both sides of this issue, Congress has chosen to require the agency to use tolerances in regulating section 346 substances. Therefore, any changes in the statute should be made by the legislature and not by the FDA or the courts.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

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No. 85-664

IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF NATIONAL PEANUT COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Food and Drug Administration is required to regulate unavoidable "added" poisonous or deleterious substances in food by adopting tolerances through formal rulemaking, rather than by adopting informal action levels which are applied on a case-by-case basis.

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On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF NATIONAL PEANUT COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

The National Peanut Council, Inc. ("NPC"), by its attorneys, files this brief as *amicus curiae* in support of the Petitioner, Frank Young, Commissioner of Food and Drugs ("FDA"), and respectfully urges this Court to issue a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit to review the judgment entered in the above-captioned case. This brief is submitted with the written consent of all parties on file with the Clerk of this Court.

INTEREST OF *AMICUS CURIAE*

The National Peanut Council, Inc. ("NPC") is a non-profit Georgia corporation, chartered in 1940, which represents and serves individuals, companies, corporations, and associations engaged in, or providing goods or services to, the production, processing, marketing, or manufacturing of peanuts and peanut products. NPC members include peanut growers and affiliated associations, shellers, custom processors, brokers, manufacturers, and international and allied entities.

The subject matter of the instant case—whether the Food and Drug Administration ("FDA") is required to regulate unavoidable "added" poisonous or deleterious substances in food by means of tolerances promulgated through formal rulemaking, rather than by informal action levels resulting in case-by-case adjudication—is of great concern to NPC, since the specific substances at issue here, "aflatoxins," are chemical byproducts of molds that grow on corn and numerous other agricultural commodities. Furthermore, NPC and its members would be adversely affected by an interpretation of the Federal Food, Drug and Cosmetic Act ("FDCA"), as amended, 21 U.S.C. §§ 301 *et seq.*, that renders adulterated all foods which contain detectable amounts of any unavoidable poisonous or deleterious substance, unless and until a tolerance for each substance and food has been established and promulgated by the FDA.

The interest of NPC is predicated upon the substantial and far-reaching consequences of the result of the instant case. The concern of the *amicus curiae* is that the Court, in formulating the principles to govern the particular dispute involved in the present case, should have the benefit of NPC's views, which may not otherwise be presented in the arguments of the parties, in order to be aware of the broader ramifications of its decision herein.

STATEMENT OF THE CASE

This case presents a challenge to the FDA's method of regulating the interstate commerce of foods which evidence any "added" poisonous or deleterious substance that is required in the production of food or that cannot be avoided by good manufacturing practices. Since the enactment of the FDCA in 1938, FDA has regulated the amounts of substances like aflatoxin principally by issuing "action levels," which announce the level of the particular substance that FDA regards as resulting in adulteration under 21 U.S.C. § 342(a)(1).

Respondents brought this suit to challenge FDA's method of regulation of aflatoxins in corn products. Respondents contended that: (1) FDA should be compelled to adopt a formal aflatoxin tolerance pursuant to 21 U.S.C. § 346, as opposed to an informally implemented action level; (2) the action level, in the alternative, should be made subject to notice-and-comment rulemaking; and (3) certain exemptions to the action level were contrary to law. The United States District Court for the District of Columbia granted summary judgment in favor of FDA on all three issues. Recognizing that an agency's interpretation of its statute is entitled to substantial deference, the court found that FDA's construction of 21 U.S.C. § 346 was reasonable and that 21 U.S.C. § 346 "confers discretionary, not mandatory, authority on the agency to establish tolerances." Pet. App. 31a-32a (footnote omitted). It also concluded that action levels were general statements of policy not requiring notice-and-comment rulemaking and that the exemptions granted were within the agency's discretion. *Id.* at 32a-34a.

The United States Court of Appeals for the District of Columbia Circuit reversed, holding that "the FDA may not proceed by means of action levels rather than toler-

ances," Pet. App. 2a, which require time-consuming and burdensome formal rulemaking procedures and induce inflexible standards. The court reiterated its holding by stating that, "since the existence of a regulation [under 21 U.S.C. § 346] operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." Pet. App. 7a.

NPC, as *amicus curiae*, fully supports Petitioner's statement of the general principles applicable to the instant case and the interpretation of the underlying statutory and regulatory scheme.

SUMMARY OF ARGUMENT

In support of Petitioner's position, NPC respectfully suggests that the Writ of Certiorari be granted as the question raised by Petitioner is substantial and of vital national importance for the following reasons:

(1) The District of Columbia Circuit's interpretation of the FDCA renders almost all foods adulterated and immediately vulnerable to enforcement action, and

(2) The District of Columbia Circuit's interpretation of the FDCA subjects all food producers, processors, and distributors to potential civil and criminal liability for the interstate commerce of agricultural commodities.

ARGUMENT

I. THE COURT OF APPEALS' INTERPRETATION OF THE FDCA RENDERS ALMOST ALL FOODS ADULTERATED AND IMMEDIATELY VULNERABLE TO ENFORCEMENT ACTION.

The court of appeals' interpretation of the FDCA, that "the FDA may not proceed by means of action levels rather than tolerances," [1] was buttressed by an argument which renders almost all foods adulterated under the provisions of the FDCA. The court stated that: "Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." Pet. App. 7a. The court interpreted 21 U.S.C. § 346 to mean that any food which contains an "added" unavoidable poisonous or deleterious substance is adulterated unless "a regulation establishing a tolerance is in effect." Pet. App. 7a. The court provided no support for its reasoning, found "little guidance in the legislative history," Pet. App. 9a, and failed to cite any supporting judicial authority for this sweeping and novel interpretation of the FDCA which threatens the nation's food supply.

A necessary implication of the court of appeals' decision is that, before a tolerance is adopted, the presence of *any* "added" poisonous or deleterious substance, even if necessary or unavoidable, renders food adulterated and, therefore, barred from shipment in interstate commerce. Because tolerances can only be adopted through the extraordinarily cumbersome and time consuming procedures

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[1] Pet. App. 2a. The court reiterated its holding by stating that "we have concluded that the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1). . . ." Pet. App. 15a.

set forth in 21 U.S.C. § 371(e), many years could well pass during which a substantial portion of the nation's food supply was technically "adulterated." It is clear that the court of appeals failed to fully comprehend the nature of aflatoxin, the practical realities of FDA's regulatory scheme, and the economics of the nation's food supply. Its decision, if not reversed, could completely eliminate the interstate commerce of many agricultural commodities, and apply severe economic forces to intrastate commerce in foods, which will cause prices of certain commodities and their nutrition-substitutes to skyrocket.

In order to clearly appreciate the national interests at stake and the magnitude of the consequences of this decision, NPC, as *amicus curiae*, proffers a brief discussion of the nature of aflatoxins and FDA's regulatory scheme.

1. *The Nature of Aflatoxins.*

The specific "added" poisonous or deleterious substances at issue here, "aflatoxins," are naturally occurring chemical substances produced by the molds *Aspergillus flavus* and *Aspergillus parasiticus*. Aflatoxins occur worldwide in many agricultural commodities; their production is favored by warm temperatures and high moisture levels typical of tropical and subtropical areas, including southern United States. In addition, *A. flavus* invasion of crops and resulting aflatoxin production has also been associated with drought-induced stress, over-maturity, and physical and biological damage.[2] Aflatoxins are frequently found in corn, cottonseed, tree nuts, figs, peanuts, grains, animal products (such as milk and milk products), and meat products of animals which have ingested aflatoxin-contaminated feeds.[3] Although considerable

[2] Diener, U.L., *Deterioration of Peanut Quality Caused By Fungi*, in PEANUTS—CULTURE AND USES, at 523, American Peanut Res. Educ. Assn. 1973; Shotwell, O.L., *Aflatoxin In Corn*, J. Am. Oil Chem. Soc. 54: 216A, 1977.

[3] Stoloff, L., *Aflatoxins—An Overview*, in MYCOTOXINS IN HUMAN AND ANIMAL HEALTH (1977); Stoloff, L., *Occurrence of Mycotoxins*

progress has been made in controlling the aflatoxin contamination of foods and feeds, detoxifying contaminated products,[4] and identifying their significant relationships with the presence of zinc and absence of phytic acid,[5] the complete prevention of mold growth and aflatoxin production in foods appears unattainable at the present time.[6] Since its discovery in the early 1960's, aflatoxin contamination has continued to concern FDA. Soon after the discovery of aflatoxins in foods FDA began a program for their control,[7] and in 1965 FDA established an informal action level of 30 parts per billion ("ppb") total aflatoxins for edible agricultural commodities. In 1969, FDA reduced the action level to its current level of 20 ppb total aflatoxins for human foods and animal feed.[8]

Action levels have permitted FDA the necessary flexibility to set realistic limits on the presence of aflatoxins and other contaminants in foods, free sufficient staff for

in Foods and Feeds, in MYCOTOXINS AND OTHER FUNGAL RELATED FOOD PROBLEMS 149 (J.V. Rodricks ed. 1976); Rodricks, J.V., *Hazards From Nature—Aflatoxins, reprinted from*, FDA CONSUMER, H.E.W. Pub. No. (FDA) 78-2102, May 1979.

[4] *Aflatoxin and Other Mycotoxins: An Agricultural Perspective*, Council for Agricultural Science and Technology, Report No. 80, December, 1979, at 1.

[5] *Soybeans Aflatoxin Control Secret*, News, Chestertown, Maryland, May 2, 1979, *Aflatoxins Continue To Be A Problem*, Countryside, August 1979, at 51.

[6] Stoloff, L., *Aflatoxins—An Overview*, in MYCOTOXINS IN HUMAN AND ANIMAL HEALTH (1977). Major causes of peanut invasion by *A. flavus* and *A. parasiticus* are plant stress, insect damage, mechanical damage, delayed drying, and inadequate ventilation.

[7] Food and Drug Administration, *Compliance Program Guidance Manual, Programs on "Mycotoxins in Foods,"* 1973. This document, or one similar to it, is released each year to provide guidance to FDA District Offices. Summaries of all aflatoxin control activities are contained in these programs.

[8] Pet. App. 22a.

important enforcement duties,[9] and, where necessary, grant exemptions[10] from regulatory action pursuant to those regulations.[11]

2. *FDA's Regulatory Scheme.*

The procedures employed in issuing action levels, under 21 U.S.C. § 342(a)(1), differ from those required for tolerances, under 21 U.S.C. § 342(a)(2)(A). Pet. 4-5, Pet. App. 22a. The most significant difference in the method of issuance is that tolerances are subject to notice-and-comment rulemaking procedures before issuance, under 21 U.S.C. §§ 346, 371(e), while comment opportunities concerning action levels are provided after issuance by FDA. FDA's method of issuing action levels affords the public substantial participation, even though action levels are not subject to the notice-and-comment rulemaking procedures of 21 U.S.C. § 371(e). To establish an action level, FDA publishes a notice in the *Federal Register* announcing the new level and the availability of all relevant data and invites public comment. 42 Fed. Reg. 52814 (Sept. 30, 1977). FDA would require several years, and incur a substantial administrative burden, to establish formal tolerances under 21 U.S.C. § 371(e).

Action levels are public statements of the exercise of FDA's substantial enforcement discretion under 21 U.S.C. § 336 of the FDCA and in furtherance of the agency's responsibilities under 21 U.S.C. § 342(a)(1). The level fixed advises the public of the point at which FDA will

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[9] *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979) (action to enjoin shipment of corn containing an amount of aflatoxin exceeding FDA's action level), *see also, United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980).

[10] Pet. App. 24a.

[11] Pet. App. 25a-26a. The FDA has granted two exemptions in eight years. The FDA's 1980 limited exemption was the underlying cause of Respondents' suit.

undertake regulatory action. It is akin to the local police department which, for reasons of resources and priorities, will not stop speeding cars unless they are traveling at speeds in excess of 55 miles per hour, even though the posted limit may be something less.

3. *Consequences of a Tolerance Requirement.*

In light of the pervasive presence of many unavoidable environmental contaminants in the air, soil, and water, most agricultural commodities will be in violation of the FDCA under the court of appeals' interpretation. Furthermore, for over ten years, FDA has publicly advanced this fact: "The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities," 42 Fed. Reg. 52814 (Sept. 30, 1977),[12] and has identified the consequences of a nondetectable-residue requirement which are strikingly similar to the consequences of a tolerance requirement:

> If a nondetectable-residue requirement were automatically applied to environmental contaminants already present in the food supply, enforcement activities could significantly disrupt the food supply. Removing food containing any detectable residue from the marketplace could lead to enforcement action against food commodities not deemed to present any significant risk to public health.

42 Fed. Reg. 17490 (April 1, 1977).

The consequences of the court of appeals' interpretation are: (1) severe FDA administrative burden caused by the promulgation requirements of formal tolerances, (2) findings that, in the absence of tolerances, many foods are adulterated and therefore barred from inter-

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[12] With respect to wildlife, FDA has asserted: "[M]ercury contamination of the aquatic habitat and thereby of fish and shellfish is ubiquitous and unavoidable . . . ." 39 Fed. Reg. 42739 (Dec. 6, 1974).

state commerce, (3) uncertainty and possible civil and criminal liability caused by the expected delay in issuing tolerances and (4) the resulting economic forces on the price of food caused by limiting the nation's food supply.

This case construes FDA's regulatory methods for *all* unavoidable "added" poisonous or deleterious substances, of which aflatoxin presence in corn is only a specific instance. Hence, the consequences of the court of appeals' interpretation must be multiplied by the enormous number of agricultural and animal commodities which may contain contaminants classified as necessary or unavoidable "added" poisonous or deleterious substances and which contaminate our air, water or soil. Therefore, if allowed to stand, the court of appeals' interpretation of the FDCA renders almost all food adulterated and immediately subject to enforcement action under the FDCA. Furthermore, due to the great number of tolerances which must be promulgated, FDA may not be able to remedy this situation for an extended period of time.

II. THE COURT OF APPEALS' INTERPRETATION OF THE FDCA SUBJECTS ALL FOOD PRODUCERS, PROCESSORS, AND DISTRIBUTORS TO POTENTIAL CIVIL AND CRIMINAL LIABILITY FOR THE INTERSTATE COMMERCE OF AGRICULTURAL COMMODITIES.

The court of appeals' interpretation of the FDCA, that absent tolerances any amount of a necessary or unavoidable environmental contaminant renders food adulterated, would severely aggravate the problems noted by Judge Frank's dissent in *United States v. 449 Cases, Containing Tomato Paste*, 212 F.2d 567 (2d Cir. 1954), until such time as FDA promulgates tolerances for all foods. The specific problems noted by Judge Frank, and compounded by the opinion below, include the possibility of dangerous administrative arbitrariness of enforcement of the FDCA without recognizable standards which

activate enforcement and lack of publication of those standards. *Id.* at 577-79. Clearly, the possible imposition of civil liability without notice of tolerances, due to the protracted promulgation requirements of formal tolerances, should be avoided as a disservice to the public and the food industry.

In addition to the imposition of civil liability without notice of enforcement tolerances, the FDCA provides, at 21 U.S.C. § 331, that the interstate commerce of any food that is adulterated is prohibited by the FDCA,[13] and provides for strict criminal liability.[14] Corporate officials, officers, and managers have been held criminally liable for placing adulterated foods into interstate commerce,[15] and this Court has held that they have a "a duty to implement measures that will insure that violations will not occur." *United States v. Park*, 421 U.S. 628 (1975).

Under the interpretation espoused by the court of appeals, the only way that corporate officials could insure that "violations will not occur" would be to halt shipment of most foods, thereby seriously disrupting the nation's food supply and causing product shortages and economic instability. Clearly, the ramifications of the court of appeals decision have not been properly considered and weighed.

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[13] *See United States v. Barnett*, 587 F.2d 252 (5th Cir.), *cert. den.*, 441 U.S. 923 (1979); *United States v. Cassaro, Inc.*, 443 F.2d 153 (1st Cir. 1971).

[14] *Triangle Candy Co. v. United States*, 144 F.2d 195 (9th Cir. 1944) (persons introducing adulterated food in interstate commerce are criminally liable, regardless of their intent or lack of knowledge as to adulteration); *United States v. Dotterweich*, 320 U.S. 277 (1943).

[15] *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S.D. Iowa 1976); *United States v. Colosse Cheese & Butter Co.*, 133 F. Supp. 953 (S.D.N.Y. 1955).

The currently enforced action levels have given the public notice of levels which FDA has determined would give rise to a violation of 21 U.S.C. § 342(a)(1) and thus ameliorates the problems identified by Judge Frank. However, the court of appeals' decision will create an opportunity for arbitrary enforcement, at least until such time as formal tolerances under 21 U.S.C. § 346 can be adopted for the broad range of environmental contaminants.

NPC is seriously concerned that the far-reaching consequences of this case be appreciated. If allowed to stand, the court of appeals' decision threatens either "a cessation of the production and shipment of all foods containing any amount of any 'added' poisonous or deleterious substance, or all segments of the food industry must act in apparent violation of the FDCA until the lengthy process of issuing formal tolerances is completed." Pet. 18.

CONCLUSION

For the reasons set forth herein, the National Peanut Council, Inc., as *amicus curiae* in support of Petitioner's position, respectfully urges this Court to issue a Writ of Certiorari to review the judgment and opinion of the District of Columbia Circuit.

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No. 85-664

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF SOUTH CAROLINA AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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STATEMENT OF INTEREST OF THE AMICUS CURIAE

In 1980, South Carolina, together with its sister states of North Carolina and Virginia, petitioned the Food and Drug Administration (FDA) for a temporary amendment of FDA's "action level"[1] for corn

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[1] FDA "action levels" are maximum permissible levels for unavoidable substances in food. FDA uses these levels for determining whether the food "may be injurious to health" and for recommending regulatory action under § 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. § 342(a)(1).

bearing small quantities of aflatoxin, a mold by-product which develops in corn in the field.

In some years, because of unusually wet or unusually dry weather conditions, the level of aflatoxin in the corn crop may exceed the 20 parts per billion (ppb) action level established in 1974 by FDA. 39 *Fed. Reg.* 42748 (December 6, 1974). When such circumstances occurred in 1980, South Carolina had to choose between either obtaining the FDA's cooperation in regulating the interstate use of corn with aflatoxin above 20 ppb or regulating the use and disposition of such corn solely within the borders of South Carolina. South Carolina chose the first course by petitioning FDA to raise the aflatoxin action level to 100 ppb for certain safe, animal feed uses of the corn in non-lactating and mature livestock and poultry, while leaving the 20 ppb action level in effect for aflatoxin on corn used as human food or as feed to dairy cattle.

South Carolina has appeared as *amicus curiae* on behalf of the Commissioner of Food and Drugs during both the United States District Court and the United States Court of Appeals proceedings.

The State of South Carolina is vitally concerned with its ability to obtain revised federal regulatory guidelines to properly regulate the temporary occurrence of a contaminant in the food supply. Thus, South Carolina sees great need and importance for FDA to be able to respond flexibly and promptly by issuing, in the *Federal Register*, a revised action level expressing FDA's view as to whether a product is adulterated under § 402(a)(1) of the FDC, 21 U.S.C. § 342(a)(1). The Court of Appeals' apparent requirement on FDA to issue a tolerance using the formal trial type

rulemaking procedures of § 701(e) of the FDCA pursuant to §§ 402(a)(2)(A) & § 406 of the Act, 21 U.S.C. §§ 342(a)(2)(A) & 346, would hamstring State and Federal regulatory bodies in directing safe uses of food unavoidably containing environmental contaminants.

1. Statement of Facts

For a number of years, FDA has maintained an action level for aflatoxin in corn at 20 ppb. An action level simply expresses FDA's policy as to the level at which the Agency considers a food to be adulterated. FDA has established action levels for a variety of food defects and contaminants including insect parts in imported spices and traces of pesticides in non-target crops. Prior to 1972, FDA refused to divulge these policy guidelines, but since that time FDA has made this information publicly available to give guidance to industry and state officials. 37 *Fed. Reg.* 6497 (March 30, 1972).

In 1980, the corn crop in the southeastern portion of the United States contained a higher than usual level of aflatoxin due to an unusual combination of early drought and late rains. Therefore, South Carolina together with North Carolina and Virginia requested FDA reconsider its enforcement policies towards such corn. The three States submitted that since corn with elevated levels of aflatoxin (100 ppb) can be safely used as feed for non-lactating animals and poultry, FDA should rule that corn with aflatoxin up to 100 ppb would not be adulterated when limited to such use while leaving intact the action level of 20 ppb for all other uses. FDA agreed. 46 *Fed. Reg.* 7447

(January 23, 1981). The Community Nutrition Institute then filed the present action in the United States District Court for the District of Columbia questioning FDA's authority to change its enforcement intentions regarding corn bearing aflatoxin without resorting to formal, trial type rulemaking pursuant to §§ 406 and 701(e) of the FDCA, 21 U.S.C. §§ 346 & 371(e).

2. Proceedings Below

The United States District Court for the District of Columbia heard the present case on cross motions for summary judgment and granted the motion filed by the FDA. The court correctly ruled that § 406 did not mandate tolerances for unavoidable poisonous or deleterious substances.

The United States Court of Appeals for the District of Columbia Circuit reversed, finding that FDA can only allow the shipment of products containing *any* food contaminant if it first promulgates a tolerance pursuant to §§ 406 and 701(e) of the Act. The Court of Appeals decision wrote § 402(a)(1) out of the FDCA and, in effect, overruled this Court's decisions in *Flemming* v. *Florida Citrus Exchange,* 358 U.S. 153 (1958), and *United States* v. *Lexington Mill and Elevator,* 232 U.S. 399 (1914).

ARGUMENT

A. When A Food Contains An Unavoidable Poisonous or Deleterious Substance For Which No Tolerance Has Been Established, Section 406 Of The Federal Food, Drug and Cosmetic Act Does Not Apply

Section 406 of the Act was added as part of the 1938 revision of the 1906 Pure Food and Drug Act.

This section, by its plain language, addresses two specific and factual circumstances. The first clause of the first sentence provides that the addition of any *unnecessary or avoidable* poisonous or deleterious substance (in any amount) renders the product adulterated under § 402(a)(2)(a) of the Act.[2] The second clause of the first sentence states that if the substance is necessary for production or unavoidable *and* a tolerance is in effect, any product which contains such substances in excess of the tolerance is adulterated under § 402(a)(2)(a).[3]

The section does not expressly address the question of those situations when the substance is unavoidable *and* no tolerance has been established. However, the second sentence in Section 406 gives guidance on how the above question is to be answered. This sentence reads: "While such a [tolerance] is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated with the meaning of clause (1) of Section 342(a) of this title." Accordingly, the sentence explains that a 406 tolerance takes the food

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[2] The clause reads: "Any poisonous or deleterious substance added to any food, *except where such substance is required in the production thereof or cannot be avoided* by good manufacturing practices, shall be deemed to be unsafe for purposes of the application of clause (2)(A) of Section 342(a) of this title . . . ." (Emphasis added).

[3] This clause reads: "but when such substance is so required or cannot be so avoided the Secretary shall promulgate regulations limiting the quantity therein . . . and any quantity *exceeding* the limits so fixed shall be deemed to be unsafe for purposes of the application of clause (2)(A) of Section 342(a) of this title . . . ." (Emphasis added).

out of § 402(a)(1). In the absence of a tolerance, it follows that the food would remain subject to § 402(a)(1). Under this section a food is adulterated "if it bears or contains any poisonous or deleterious substance *which may render* it injurious to health. . . ." Section 402(a)(1) (emphasis added).

This conclusion is supported by this Court's opinion in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958). There, this Court held that § 406 carved out specific exceptions to the general adulteration provision found in § 402(a)(1). "The existence of a tolerance is specifically stated in § 406(a) [currently 406] *only to give sanction to what would otherwise amount to adulteration within the terms of § 402(a)(1). Id.* at 166 (emphasis added). When § 406 does not apply, § 402(a)(1) will govern.[4] To hold § 406 covers *all* poisonous or deleterious substances would write § 402(a)(1) out of the statute entirely. Unfortunately, the Court of Appeals below did so hold.

B. The Court of Appeals Incorrectly Held A Food Containing *Any* Amount Of A Poisonous or Deleterious Substance Is Adulterated

The weakness of the Court of Appeals' reasoning is that it presumed any amount of a poisonous or deleterious substance rendered the food adulterated. Slip Op. at 7 (*Reprinted* in Petition For Writ of Certiorari at 7a). However, under § 402(a)(1) of the FDCA, as interpreted by this Court in *United States*

[4] Additionally, the legislative history makes clear that § 406 merely "authorizes," but not requires FDA to establish tolerances. See, S. Rept. No. 493, 73rd Cong., 2d Sess. 4 (1934).

v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914),[5] the mere presence of a poisonous or deleterious substance (if unavoidable) does *not* render a product adulterated; rather, the substance must be present in such a quantity which may render the product injurious to health. *Id.* at 410. Accordingly, in situations where the poisonous or deleterious substance is unavoidable and no tolerance has been established, the food is not adulterated unless the quantity is sufficient so that the product "may be injurious" to health. The mere presence of an unavoidable poisonous or deleterious substance alone does not render a product adulterated under the *Lexington Mill* opinion.

C. The Court of Appeals, By Ignoring § 402(a)(1) and the Supreme Court's Decision in *United States* v. *Lexington Mill & Elevator Co.*, Misconstrued FDA's Action In This Controversy

Contrary to the decision below, FDA did not authorize the shipment of adulterated product. FDA addressed the question of whether a certain level of aflatoxin (100 ppb) "may render" corn injurious to health, when used as feed for mature non-lactating cattle and poultry. In its determination that the product could be shipped, FDA did *not* state the product was adulterated but could be shipped nonetheless; FDA stated that it could not conclude that the 100 ppb level for those uses "may render" the product injuri-

[5] The *Lexington Mill* case involved § 7 of the Pure Food and Drugs Act of 1906 (34 Stat. 769) which was the predecessor provision to the current § 402(a)(1) of the FDCA. Yet, the *Lexington Mill* decision retained its applicability and vitality after the 1938 revision. *See, e.g., Flemming* v. *Florida Citrus Exchange*, 358 U.S. at 161 (1958).

ous to health under § 402(a)(1) of the Act. Therefore, the product is not adulterated. FDA simply recognized it lacked the scientific grounds and evidence to proceed against the product. Since FDA did not find the product to be adulterated, it was not mandated to establish a tolerance. *Cf. Flemming* v. *Florida Citrus Exchange,* 358 U.S. 153 (1958).

D. The Decision Unduly Hinders South Carolina In Its Regulatory Enforcement

Not only does the Court of Appeals decision rewrite the FDCA, it creates an enormous regulatory burden on South Carolina. South Carolina has the same interest as the federal government in protecting its citizens from products which contain poisonous or deleterious substances which may render the product injurious to health. However, this interest would not be served if the Court of Appeals holding—that all products which contain even a trace of poisonous or deleterious substances are adulterated unless FDA establishes formal tolerances—is allowed to stand.

First, since the decision only applies to products shipped in interstate commerce,[6] farmers would be prohibited from shipping in interstate commerce under the decision. This means the products would remain within the state. This would leave South Carolina with the entire regulatory responsibility and burden for ensuring the products are not used in ways which threaten the public health.

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[6] FDA's authority to regulate or prohibit the shipment of adulterated food is limited to either the interstate shipment of the product or movement of the components of the food product in interstate commerce. *See*, §§ 301(a) & (k) of the FDCA, 21 U.S.C. §§ 331(a) & (k).

Second, the Court of Appeals' decision would prohibit FDA from indicating what levels it feels constitute adulteration under § 402(a)(1)—this could be construed as an impermissible action level—and South Carolina would be denied FDA guidance on what levels and uses are safe. South Carolina does not have the resources of FDA in these matters, thus compromising the public health.

Third, the Court of Appeals' decision would deny South Carolina the opportunity to work with FDA to develop plans for the distribution of the product which, through an Act of God, contains unavoidable poisonous or deleterious substances but which do not threaten the public health.

The Court of Appeals felt such concerns could be answered if FDA simply established formal tolerances. In reality, such would not occur. Under 701(e) of the Act, 21 U.S.C. § 371(e), tolerances are subject to formal adjudicative rulemaking procedures, not simple notice and comment rulemaking. This procedure is extremely time-consuming. Indeed, on the simple question of whether peanut butter should contain 87% or 90% peanuts, the FDA formal rulemaking transcended ten years and accumulated over 32,000 pages of hearing transcript. *See* Hamilton, *Rulemaking on a Record by the Food and Drug Administration,* 50 Tex. L. Rev. 1132 (1972). Even if a tolerance was eventually established, FDA would lack the flexibility either to respond to a request for modification in light of unforeseen circumstances, such as the South Carolina 1980 request, or to tighten the tolerances in light of new data to better protect the public health. South Carolina should not be forced to wait ten years to obtain FDA guidance whether a particular use of a

perishable product violates § 402(a). Nor, should the public be exposed to ten years of unsafe levels of poisonous or deleterious substances where new scientific evidence simply demonstrates that a tolerance is outdated.

CONCLUSION

For the above reasons, the State of South Carolina respectfully requests this honorable Court grant the Petitioner's Request for a *Writ of Certiorari.*

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On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF AMICUS CURIAE NATIONAL FOOD PROCESSORS ASSOCIATION IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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BRIEF OF AMICUS CURIAE NATIONAL FOOD PROCESSORS ASSOCIATION IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

STATEMENT OF INTEREST OF AMICUS CURIAE

Amicus submits this brief in support of the petitioner Frank Young, Commissioner of Food and Drugs. Consent to file this brief has been obtained from counsel for all parties and has been filed with the Clerk of this Court.

The National Food Processors Association ("NFPA") is a scientifically based trade association representing almost 600 member companies that pack a broad range of processed-prepared food products for distribution throughout the country and the world. A substantial portion of these processed products are prepared from fruits, vegetables, and other raw agricultural commodities which in their growing state are exposed to unintended and unavoidable contaminants in the natural environment and which thereby contain extremely small but detectable levels of any number of such environmental contaminants that generally cannot be removed by processing operations. The detection, identification, and possible reduction of these environmental contaminants in raw and processed foods has for many years been an important aspect of the work carried on in the three scientific laboratories of NFPA.[1]

The food processor members of NFPA and the Association itself would thus be very substantially affected by an interpretation of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§ 301-392 (1982) ("the Act") that regards as adulterated all foods containing detectable amounts of any unavoidable environmental contaminant unless and until a formal tolerance has been established for

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[1]The Association was founded in 1907 as the National Canners Association, growing out of the collective canning industry support for enactment of the Food and Drug Act of 1906. Since its first scientific research laboratory was opened in 1913 the Association has been actively involved in research, testing and training programs that contribute significantly to the safety of the food supply. The Association has continuously maintained its interest in food safety legislation and regulatory programs, including the Federal Food, Drug, and Cosmetic Act of 1938 and subsequent amendments. *See, e.g.*, the references to the involvement of the Association in the 1954 pesticide amendments to the Act, cited in the Government's Petition (Pet. 11-12 n.5).

each such contaminant pursuant to costly, burdensome, and time-consuming evidentiary hearing procedures.

ARGUMENT

Congress in § 406 of the Act, 21 U.S.C. § 346, directed that the FDA "shall promulgate regulations" establishing tolerances for poisonous or deleterious substances required to produce food or unavoidable in its production "to such extent as [it] finds necessary for the protection of public health . . .." The court of appeals read these words as a command to the FDA to promulgate such regulations in any and all circumstances, the qualifying "to such extent" clause conferring discretion only as to the substance of the regulations that must be promulgated. The Government says in its Petition that the court's reading of § 406 is a permissible one, though urging correctly that, even if permissible, the court's reading could not lawfully be substituted for the agency's own permissible, reasonable reading: that Congress has given FDA the customary agency discretion to decide whether — "to [what] extent" — the protection of the public health requires, in any particular circumstance, a formal tolerance regulation. (Pet. 8).

The court of appeals reading is not even permissible unless one improperly isolates § 406 from § 402(a), 21 U.S.C. § 342(a). The effect of the court of appeals reading is to leave the opening clause of § 402(a)(1) — the topic sentence of the whole statutory scheme we are dealing with — without any application. Congress cannot reasonably be taken to have legislated in that way — to have written a statute that states a fundamental rule governing the adulteration of food that might as well not have been stated because all possible cases of adulteration are covered by other more specific rules.

The statutory question presented by the Government's Petition is thus substantial, however the court of appeals

facile "shall-means-shall" reasoning may mask the fact. We explain the substantiality of the question in Part II of the Argument hereunder.

The question is also of the most urgently serious national importance. The court of appeals repeatedly stated that the necessary implication of its decision that the FDA must prescribe formal tolerances for contaminants necessarily or unavoidably added to food was that in the absence of any tolerance, the presence of *any* such necessary or unavoidable substance makes the food adulterated and therefore barred from the channels of commerce. In Part I of the Argument we demonstrate that, if the decision below is allowed to stand, the result will be either an unimaginable and, in fact, insufferable disruption of the nation's food supply or a massive turning of a blind eye to the requirements of the law, with all the impairment of the national respect for law and invitation to selective law enforcement that any such conduct entails.

I. THE QUESTION PRESENTED BY THE PETITION IS OF VITAL NATIONAL IMPORTANCE

Fundamental to the court of appeals decision below is its holding that the presence of an added poisonous or deleterious environmental contaminant in a food renders the food adulterated, unless a tolerance has been adopted under § 406 of the Act.[2] In the final section of its opinion the court

[2]The conclusion by the court that the aflatoxin action level is invalid because the Act does not permit shipment of food containing safe but detectable levels of an environmental contaminant in the absence of a § 406 tolerance is described in the Government's Petition as "one of the two bases for the decision" or as perhaps "dictum." (Pet. 17-18). But the court below left no doubt as to what it regarded as "the issue at hand" — "the FDA's authority *vel non* to allow shipment of adulterated foods without the establishment of tolerances." (Pet. App. 15a). The opinion below is reported at Community Nutrition Institute v. Young, 757 F.2d 354 (D.C. Cir. 1985).

described its holding as follows:

> "[W]e have concluded that the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1) . . .." (Pet. App. 15a).

The court *repeatedly* emphasized that FDA's error was to promulgate action levels that purport to permit the shipment of food containing some amount of an environmental contaminant without the adoption of a § 406 tolerance.[3]

This aspect of the opinion below involves a serious misreading of the adulteration provisions of the Act that is at odds with the statutory language, the legislative history, and the agency's long-standing and consistent interpretation of the Act. Further, the court of appeals did not address, or apparently even recognize, the overwhelmingly adverse impact that its interpretation would have on the food industry, the FDA, and the consuming public.

[3]For example: "CNI argues that the Secretary is statutorily obligated to issue regulations embodying a tolerance for the substance before the product may lawfully be introduced into interstate commerce." (Pet. App. 5a). "[T]he statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." (Pet. App. 7a). Section 306 does not support FDA, because "[t]hat section does not . . . allow the shipment of aflatoxin-tainted corn without the establishment of a tolerance." (Pet. App. 8a). "[W]ithout the tolerance, shipment of the food would not be allowed." (Pet. App. 10a). Cited cases do not support FDA, since they do "not, in our view, speak to the agency's refusal to establish a tolerance while permitting shipment." (Pet. App. 12a). "The court [in *United States v. Goodman*] said nothing as to permission to ship without the establishment of tolerances." (Pet. App. 13a).

Of overriding significance is the fact that virtually all raw agricultural commodities[4] and processed products prepared from them contain one or more unavoidable "added" environmental contaminants, at safe but nevertheless detectable levels. The pivotal term "added" is not defined in the Act, but FDA has consistently maintained that it "is a statutory term of art encompassing all ingredients which are not inherent and intrinsic parts of a food."[5] Accordingly, the FDA regulations define an "added" poisonous or deleterious substance as one that "is not a naturally occurring" substance, and define a "naturally occurring poisonous or deleterious substance" as "a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination." 21 C.F.R. § 109.3(c) and (d). That is not a compelled interpretation of the Act. There is a doubtful difference between an inherent part of a food and an "environmental" contaminant such as aflatoxin, which occurs in nature and affects corn because of natural growing conditions. (Pet. App. 3a n.2). The result of the FDA's interpretation is enormously to enlarge the number of contaminants that the agency must deal with as "added" substances. The courts have accepted the FDA's broad definition of the term "added," except that they have required that the contaminant present in the food be attributable at

[4]The term "raw agricultural commodity" is defined in § 201(r), 21 U.S.C. § 321(r), to mean "any food in its raw or natural state."

[5]39 Fed. Reg. 42743 (Dec. 6, 1974). The preambles to the proposed and final regulations dealing with added poisonous or deleterious substances in food set forth at length the basis for the extremely broad scope that FDA attributes to the term "added." *Id.* at 42743-44; 42 Fed. Reg. 52814-16 (Sep. 30, 1977).

least in minute part to the acts of man, whether by deliberate use or by accidental occurrence.[6]

In view of the extremely broad scope of contaminants that are regarded as "added poisonous or deleterious substances," it is not surprising that the FDA regulations take into account the ubiquity and unavoidability of these substances in foods that are raised in or procured from the natural environment:

> "The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities." 42 Fed. Reg. 52814 (Sep. 30, 1977).[7]
>
> * * *
>
> "[M]ercury contamination of the aquatic habitat and thereby of fish and shellfish is ubiquitous and unavoidable . . .." 39 Fed. Reg. 42739 (Dec. 6, 1974).
>
> * * *
>
> "If a nondetectable-residue requirement were automatically applied to environmental contaminants al-

[6]United States v. Anderson Seafoods, Inc., 622 F.2d 157, 161 (5th Cir. 1980) (traces of mercury in fish from both natural and human sources regarded as "added"); Continental Seafoods, Inc. v. Schweiker, 674 F.2d 38, 43 (D.C. Cir. 1982) (salmonella in fish held to be "added" on the ground that salmonella "can result" from insanitary processing procedures).

[7]This statement established the factual base upon which FDA relied in promulgating its procedures relating to the regulation of unavoidable environmental contaminants in foods. 21 C.F.R. Part 109. The court below never refers to these FDA regulations or the preambles that set forth their factual and legal basis, in spite of the fact that the specific action levels invalidated by the court of appeals were adopted in explicit reliance on those regulations.

ready present in the food supply, enforcement activities could significantly disrupt the food supply. Removing food containing any detectable residue from the marketplace could lead to enforcement action against food commodities not deemed to present any significant risk to public health." 42 Fed. Reg. 17490 (April 1, 1977).

The action levels actually promulgated by FDA for a broad range of substances and categories of food products are indicative of the pervasiveness of environmental contaminants in the food supply. Aflatoxin is just one of many extremely widespread and unavoidable "added" contaminants that are found in a broad range of agricultural commodities.[8] The Government's Petition lists the environmental contaminants other than pesticide residues for which action levels have been promulgated by FDA. (Pet. 16 n.8). Informal action levels have also been promulgated for a number of unavoidable pesticide residues that are subject to regulation under § 406, including aldrin, dieldrin, BHC, chlordane, DDT, DDE, TDE, DBCP, endrin, fenthion, heptachlor, heptachlor epoxide, kepone, lindane, mirex, toxaphene, and EDB, in one or more of virtually every agricultural commodity.[9] If foods containing these safe but

[8]*See, e.g.*, 39 Fed. Reg. 42748-51 (Dec. 6, 1974).

[9]Section 408, 21 U.S.C. § 346a, provides for the issuance of tolerances for residues of a pesticide in crops for which the pesticide is registered. Unavoidable pesticide residues in non-target commodities are not regulated under § 408, but instead are subject to § 402(a)(1), 21 U.S.C. § 342(a)(1) (and any action levels that may be adopted) or § 406 if a tolerance is adopted. As stated by the FDA in proposing the regulations applicable to unavoidable environmental contaminants, "tolerances or action levels [for pesticide residues] properly recognize the problem of environmental contamination caused by drift of a pesticide from one area to another, or the persistence of the chemical in the environment over a period of time." 39 Fed. Reg. 42745 (Dec. 6, 1974).

detectable levels of environmental contaminants were removed from the market, because of the absence of formally promulgated § 406 tolerances, the impact on the food supply, the food industry, and the consuming public would be so drastic as to be economically and socially intolerable.

Under the reading of the Act advanced by the court of appeals, all shipments in interstate commerce of raw and processed foods containing detectable residues of listed and unlisted environmental contaminants must be deemed to be adulterated and in violation of the Act. The packing, processing, and distributing companies responsible for such shipments will thus be subject to the criminal sanctions of the Act, as will the individual company officials who are deemed to bear a responsible relationship to the violative act.[10] The assumption advanced in the Government's Petition that FDA would not enforce the Act in such a way as seriously to disrupt the food supply (Pet. 18) has a hollow ring to food company officials who have been explicitly warned by this Court that "the Act imposes [on them] not only a positive duty to seek out and remedy violations when they occur but also, and primarily, *a duty to implement measures that will insure that violations will not occur.*"[11]

If the court of appeals interpretation is allowed to stand, there is no way that the stern strictures of this Court's

[10]United States v. Park, 421 U.S. 658 (1975).

[11]*Id.* at 672 (emphasis added). The tension between the teaching of *Park* and the opinion below gives rise to significant constitutional questions. *Cf.* Lambert v. California, 355 U.S. 225, 229 (1957):

> "As Holmes wrote in The Common Law, 'A law which punished conduct which would not be blameworthy in the average member of the community would be too severe for that community to bear.' *Id.*, at 50. Its severity lies in the absence of an opportunity either to avoid the consequences of the law or to defend any prosecution brought under it."

opinion in *Park* can be reconciled with the practical need to continue production and distribution of the food supply while the FDA, the industry, and the public are working their way through costly and time-consuming trial-type hearings for each one of the currently listed and the many unlisted environmental contaminants in virtually all raw agricultural products. The Government's Petition documents the literal impossibility of the FDA's initiating and completing within the foreseeable future proceedings for the establishment of formal tolerances for all detectable environmental contaminants. (Pet. 15-16).

The court below was apparently unaware of the protracted rulemaking procedures that must be observed in the promulgation of § 406 tolerances for each contaminant and for each food commodity. In describing the nature of the case, the court stated that the plaintiffs "brought suit in federal district court to require the FDA to adopt, *by way of notice-and-comment rulemaking*, formal aflatoxin levels or 'tolerances,' as opposed to informally implemented action levels." (Pet. App. 2a) (emphasis added). The fact is that § 406 tolerances may not be adopted by way of simple notice-and-comment rulemaking under § 701(a),[12] but instead may be adopted only pursuant to the far more complex and protracted procedures prescribed in § 701(e). These are, to be sure, initiated by notice and comment, but they also include an evidentiary hearing and the other time-consuming features of a determination that is required to be on the record, if such a determination is demanded by any person who will be adversely affected.[13] Whatever may be

[12]21 U.S.C. § 371(a), which vests in the Secretary "authority to promulgate regulations for the efficient enforcement of the Act." *See, e.g.*, Abbott Laboratories v. Gardner, 387 U.S. 136, 138 (1967).

[13]21 U.S.C. § 371(e), which provides in relevant part that, "Any action for the issuance, amendment, or repeal of any regulation under section . . . 346 . . . of this Act shall be begun by a proposal" that initiates the full procedures of 21 U.S.C. § 371(e), (f) and (g).

said for the wisdom or efficiency of these rulemaking-on-a-record procedures, there can be no doubt that the process necessarily entails a substantial investment in time and resources by FDA and the interested public.[14]

In view of the total impracticability of § 406 tolerances being promulgated for all unavoidable environmental contaminants within the next few years, if ever, this case thus involves far more than a question of the particular rulemaking procedures employed by FDA. At the heart of the case is a substantive issue of law that bears importantly on the administration of the Act, the integrity of the nation's food supply, and the criminality of the everyday practices of thousands of food companies and their responsible officials.

II. THE QUESTION PRESENTED BY THE PETITION IS SUBSTANTIAL

The basic conclusion upon which the opinion below rests is that the aflatoxin action levels at issue are invalid because the Act does not "allow the shipment of aflatoxin-tainted corn without the establishment of a tolerance."[15] The court of appeals justified this conclusion almost solely on the ground that the "presence of the critical word 'shall' [in the

[14]*See, e.g.*, National Nutritional Foods Ass'n v. FDA, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975); Merrill and Hutt, *Food and Drug Law* 895-96 (1980); Hamilton, *Rulemaking on A Record by the Food and Drug Administration*, 50 Tex. L. Rev. 1132 (1972); Note, *FDA Rule-Making Hearings: A Way Out of the Peanut Butter Quagmire*, 40 Geo. Wash. L. Rev. 726 (1972); Administrative Conference of the United States, Recommendation No. 71-7, 2 Recommendations and Reports of the Administrative Conference of the United States 42 (1973); Austern, *Is Government by Exhortation Desirable?*, 22 FDC L.J. 647 (1967); Pendergast, *The Nature of Section 701 Hearings and Suggestions for Improving the Procedures for the Conduct of Such Hearings*, 24 FDC L.J. 527 (1969).

[15]Pet. App. 8a. See also the excerpts from the opinion cited at p. 5 n. 3, *supra*.

second clause of § 406] suggests a directive to the Secretary to establish a tolerance, if a food with an unavoidable poisonous or deleterious substance is to be considered unadulterated." (Pet. App. 6a).

Before turning to the fundamental error in the court's reading of the Act, it may be helpful to review the language of §§ 402(a) and 406 as it has been interpreted by FDA and understood by the affected industry since its enactment in 1938. The first clause of § 402(a)(1) states the general standard that a food shall be deemed adulterated if it contains any poisonous or deleterious substance which may render it injurious to health. This Court has held that under this language the poisonous or deleterious substance must be present in sufficient quantity that it might make the food injurious to health.[16] Thus, quantitative action levels are wholly appropriate as agency guidelines for the enforcement of § 402(a)(1). Because the second clause of § 402(a)(1) prescribes a somewhat more lenient standard for poisonous or deleterious substances that are "not added,"[17] the first clause applies only to "added" poisonous or deleterious substances.[18]

[16]In United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 410-11 (1914), the Supreme Court held that under the 1906 Act the simple existence of an added poisonous or deleterious substance in a food did not render the food adulterated. The substance must be shown to be present in such quantity that might render the product injurious to health. In Flemming v. Florida Citrus Exchange, 358 U.S. 153, 161 (1958), this Court held that the rule of *Lexington Mill* continued to apply under the first clause of § 402(a)(1).

[17]The second clause provides that "in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not *ordinarily* render it injurious to health." 21 U.S.C. § 342(a)(1) (emphasis added).

[18]The difference between "added" and "not added" substances is discussed at p. 6, *supra*.

For a few categories of added poisonous or deleterious substances this general safety standard in the first clause of § 402(a)(1) is explicitly displaced by a more specific standard contained elsewhere in the statute.[19] In addition, § 402(a)(2)(A) provides that food is deemed adulterated if it contains "any added poisonous or deleterious substance . . . which is unsafe within the meaning of section 406."[20] This latter section provides that an added poisonous or deleterious substance shall be deemed to be "unsafe" for purposes of § 402(a)(2)(A) under two circumstances: under the first clause of § 406, *any* amount of such a substance is unsafe if it is *not* required in the production of the food or is *not* unavoidable; and under the third clause of § 406, if a tolerance has been adopted for an added poisonous or deleterious substance that *is* required in production or *is* unavoidable, the substance is deemed unsafe if it exceeds the amount prescribed in the tolerance. While a tolerance is in effect, a food containing the substance is not considered adulterated under the general safety standard of § 402(a)(1).[21]

On its face § 406 prescribes no safety standard for required or unavoidable added poisonous or deleterious sub-

[19]More specific statutory standards are prescribed in §§ 402(a)(2)(B) and 408 for registered pesticides in foods; in §§ 402(a)(2)(C) and 409 for food additives in foods, in § § 402(c) and 706 for color additives; and in §§ 402(a)(2)(D) and 512 for new animal drugs. 21 U.S.C. §§ 342, 346a, 348, 376, and 360b. These substances are also excluded from § 402(a)(2)(A).

[20]Sections 402(a)(1) and 402(a)(2)(A) thus both apply to added poisonous or deleterious substances not otherwise excluded, but they prescribed different tests of adulteration, and the latter applies *only* when § 406 explicitly deems a substance to be unsafe.

[21]This provision has the effect of avoiding a conflict between the somewhat different safety standards in §§ 402(a)(1) and 406, if the prescribed tolerance is higher than the level that would be permitted under § 402(a)(1).

stances for which a tolerance has not been promulgated. To repeat, § 402(a)(2)(A) treats a food as adulterated only if it contains a substance "which is unsafe within the meaning of section 406." Section 406 explicitly sets forth only two circumstances in which an added substance is deemed to be "unsafe," neither of which applies to required or unavoidable substances for which no tolerance has been prescribed. This apparently deliberate omission does not leave a regulatory gap, however, since the general standard for added poisonous or deleterious substances in the first clause of § 402(a)(1) remains applicable to substances not covered by § 406 or by a more specific statutory standard.

The court of appeals interpretation of these statutory provisions derives from the directive in the second clause of § 406 that "the Secretary shall promulgate regulations" limiting the quantity of a required or unavoidable added substance in a food "to such extent as he finds necessary for the protection of public health."[22] The use of "shall," the court states, "plainly suggests a directive to the Secretary to establish a tolerance, if a food with an unavoidable poisonous or deleterious substance is to be considered unadulterated."[23] But the language of § 406 simply does not

[22]As made clear in the Petition, the "to such extent" clause may reasonably be read as either a precondition for the adoption of a tolerance (the FDA interpretation) or as a prescription of the level to be adopted (the court of appeals interpretation). (Pet. 8). But even if the court of appeals interpretation is accepted in this respect, so that the Secretary is directed to prescribe a tolerance for *every* unavoidable environmental contaminant, nothing in § 406 or elsewhere in the Act supports the court's conclusion that in the absence of a tolerance § 402(a)(1) must be totally disregarded and that any detectable amount of an environmental contaminant renders a food adulterated.

[23]Pet. App. 6a (emphasis added). The court's use of "suggests" apparently reflects its recognition that § 406 does not on its face state that an added required or unavoidable substance is unsafe in the absence of a tolerance, but the opinion does not otherwise attempt to deal with this statutory omission.

say that a food is adulterated or unsafe if it contains an added unavoidable substance for which no tolerance is in effect. The court reads such a requirement into § 406, and in doing so reads the first clause of § 402(a)(1) out of the Act altogether, for this latter provision is of no effect whatever if all added poisonous or deleterious substances — whether or not required or unavoidable, and whether or not a tolerance has been prescribed — are governed by §§ 406 and 402(a)(2)(A).[24] The court's interpretation clearly offends the "well-settled rule that all parts of a statute, if possible, are to be given effect." *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490, 513 (1981); *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 163 (1982).

The court of appeals purported to find support for its reading of § 406 in the "overall structure" of the section, and in particular in the second sentence, which in the court's words provides "that, when a regulation establishing a tolerance is in effect, such food will not be considered adulterated." (Pet. App. 7a). On this basis, the court concluded:

> "Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." *Id.*

In both of these quoted excerpts the court's paraphrases of the second sentence of § 406 omitted the concluding phrase of that sentence — "within the meaning of clause (1)

[24]If § 402(a)(1) was intended by Congress to apply only to "not added" substances, the section would have been written without the first clause. Particularly since Congress enacted § 402(a)(1) in this form and § 406 at the same time (in 1938), it is unreasonable to conclude that Congress intended for § 406 to render the first clause of § 402(a)(1) totally ineffective.

of section 402(a)."[25] This omission was apparently not inadvertent, for when the court earlier quoted § 406 at length in its opinion, it elided from the second sentence the phrase "within the meaning of clause (1) of section 342(a) of this title." (Pet. App. 4a). This suggests that the court simply did not fully understand the statutory scheme. The ultimate standard for a food is adulteration. The mere existence of a formal tolerance level for a contaminant, of course, does not prevent a food containing any quantity of the contaminant from being adulterated. If the tolerance level is exceeded, the contaminant is "unsafe" under § 406 and therefore the food is adulterated under § 402(a)(2). The statute provides that the food is not adulterated under § 402(a)(1) if a tolerance is in effect in order to assure that a food will not be deemed adulterated *under § 402(a)(1)* when the contaminant level in the food is at or below that prescribed in a § 406 tolerance.

The court's misunderstanding may have contributed to the basic logical fallacy in the indented sentence quoted above. From the statement, "If a tolerance *is* in effect, then a food containing the substance *shall not* be considered adulterated" (if A, then not B), the court infers "A tolerance *is not* in effect, therefore a food containing the substance *shall* be considered adulterated" (not A, therefore B). The major premise is wrong because it misstates the statute. And the laws of logic in any event deny the validity of the court's inference[26] and confirm the statutory interpretation

[25]The second sentence reads in full: "While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a)."

[26]An argument of this form is said to commit the Fallacy of Denying the Antecedent. Copi, *Introduction to Logic*, 234, 274 (1972).

that if no tolerance is in effect for an unavoidable added substance, § 406 does not apply and the general safety standard of § 402(a)(1) governs.

The court of appeals interprets § 406 as if it provided that an added unavoidable poisonous or deleterious substance shall be deemed unsafe *unless* a tolerance is in effect. But when Congress has intended to impose such a requirement, it has done so explicitly, not by implication or "suggestion." Sections 408(a), 409(a), and 706(a) provide that a pesticide, or a food additive, or a color additive shall be deemed to be unsafe "unless" a lawfully prescribed tolerance or exemption is in effect.[27] The wording of each of these provisions indicates that they were to some extent modeled on the language of § 406, but in each case the "unless" clause — not present in § 406 — was added. The court of appeals opinion

[27]21 U.S.C. §§ 346a(a), 348(a), 376(a). The regulatory regimes of §§ 408, 409 and 706 were enacted by Congress to establish premarket approval systems for these three categories of deliberately used or added substances, and it was thus important to provide that the presence of one of these substances in a food without a tolerance being effective would render a food adulterated. Each of these amendments necessitated the creation of an elaborate bureaucratic machinery and the promulgation of literally hundreds of regulations set forth in a total of more than 750 pages of the Code of Federal Regulations. 40 C.F.R. Part 180, pp. 216-379 (tolerances for registered pesticides deliberately used on raw agricultural commodities); 21 C.F.R. Parts 170-193, pp. 5-494 (food additive regulations); 21 C.F.R. Parts 70, 71, 73, 74, 80, 81, 82, pp. 229-341 (color additive regulations). The court of appeals opinion would require the creation of a similar bureaucracy and the promulgation of an equivalent volume of regulations for environmental contaminants if the unavoidable presence of these substances in foods is to be legitimized. As previously noted, the only alternatives would be for food companies to halt the production and shipment of most foods, or to ship adulterated foods knowingly and deliberately — a practice which this Court has severely warned against in the *Park* case. *See* p. 9, *supra*.

does what Congress deliberately decided not to do — interpret § 406 as if it read exactly like §§ 408(a), 409(a), and 706(a).

In summary, as interpreted by FDA the general safety standard in the first clause of § 402(a)(1) remains applicable to any required or unavoidable added poisonous or deleterious substance — such as an environmental contaminant — for which a tolerance has *not* been prescribed under § 406[28] (and which is not subject to the more specific standards of §§ 408, 409, 706 or 512). If the FDA can demonstrate in court that a food contains an amount of such a substance which may render the food injurious to health, the food will be deemed to be adulterated and subject to appropriate enforcement action. If the amount of such substance in a food is below the amount that may render it injurious to health, the product is lawful. The action levels promulgated by the FDA for certain environmental contaminants provide notice to the industry and the public of the amounts of such substances in food above which enforcement action will be taken under § 402(a)(1).[29]

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[28]"[T]he act clearly contemplates that the Government may proceed against a contaminated food under section 402(a)(1) of the act when no tolerance is effective." 42 Fed. Reg. 52818 (Sep. 30, 1977). The legislative history set forth in the Government's Petition demonstrates that the FDA interpretation of the Act was shared by Congress and the food industry, including the National Canners Association and its counsel. (Pet. 11-12 n.5).

[29]*See* Judge Frank's persuasive dissent in United States v. 449 Cases, etc., 212 F.2d 567, 575 (2d Cir. 1954), as to the importance of providing public notice of enforcement standards. The action levels promulgated by FDA generally reflect the agency's judgment as to what amount of a contaminant may render a food injurious to health. In some instances they also take into account the unavoidability of the substance and are thus a reflection of the agency's enforcement discretion under § 306, 21 U.S.C. § 336. *See* 39 Fed. Reg. 42745 (Dec. 6, 1974) (third column).

The court of appeals decision below totally disrupts this carefully wrought statutory scheme and should not be permitted to stand.

CONCLUSION

For the foregoing reasons, the Petition for Writ of Certiorari should be granted.

Respectfully submitted,

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No. 85-664

IN THE
Supreme Court of the United States
October Term, 1985

FRANK YOUNG, Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF AMICI CURIAE AMERICAN FEED INDUSTRY ASSOCIATION AMERICAN MEAT INSTITUTE NATIONAL BROILER COUNCIL NATIONAL COTTONSEED PRODUCTS ASSOCIATION NATIONAL TURKEY FEDERATION IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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STATEMENT OF INTEREST

Amici submit this brief in support of the petitioner Frank Young, Commissioner of Food and Drugs. Consent to file this brief has been obtained from counsel for all parties and has been filed with the Clerk of this Court.

The several trade associations joining in this brief are spokesmen for a broad array of agricultural interests that will be adversely affected if the court of appeals' decision is allowed to stand. The American Feed Industry Association is the national trade association representing the interests of those involved in the production and sale of animal and poultry feeds. The American Meat Institute is the national trade association representing packers and processors of red meat and red meat products. Its nearly 500 members produce and ship meat products throughout the United States and internationally. The National Broiler Council is the national trade association whose members represent the processors of more than 80 percent of the chicken consumed in the United States, as well as a significant number of companies that supply feed, packaging material and other products necessary in the production of chicken. The National Cottonseed Products Association is the national organization of firms and individuals engaged since its founding in 1897 in the processing of cottonseed and the marketing of its products, which include cottonseed meal, a rich source of protein which is used as a feed for livestock. The National Turkey Federation is the national trade association representing producers of turkeys and turkey products.

As the Government recognized in its Petition, "[i]n the production of food, it is often impossible to avoid the presence of small quantities of added substances that may be harmful to human health if taken in sufficient amount." (Pet. at 7.) Amici agree and accordingly are concerned that the court of appeals' decision in *Community Nutrition Institute v. Young* will have far reaching and adverse effects on American agriculture. The presence of ubiquitous environmental contaminants in raw agricultural commodities has implications which extend far beyond the crops themselves. An examination of the various stages of the food chain from growing crops to manufacturing meat and poultry products illustrates the pervasive effect of the court of appeals' decision on products containing minute quantities of unavoidable environmental contaminants.

Environmental contaiminants can be present at low levels even in the seed purchased by the farmer, and they remain in the crop as it matures. Crops can become further contaminated prior to harvest from natural contaminants such as aflatoxin,[1] or by contaminants which have been placed in the environment by man. When the crops are harvested and first processed, some environmental contaminants can be removed. However, despite the use of state-of-the-art equipment and processes, some contaminants such as aflatoxin cannot be totally eliminated by current manufacturing practices. To the extent the contaminants cannot be removed, it is imperative that the farmer or processor have guidance in determining whether the trace amounts of the contaminant are above the safety threshold so as to render the product adulterated under the Federal Food, Drug, and Cosmetic Act ("FDCA"). In the absence of such guidance, the processor is given the unwelcome choice of either destroying the crop if any residue is found or to ship and take the risk that the Food and Drug Administration ("FDA") would initiate regulatory action against the processor's shipment.[2]

---

[1]Aflatoxin is a carcinogenic mold by-product commonly found on such crops as corn, cotton, and peanuts.

[2]The shipment of "adulterated" food can subject the responsible individuals to criminal penalties pursuant to Section 303 of the FDCA, 21 U.S.C. § 333, or an injunction pursuant to Section 302 of the FDCA, 21 U.S.C. § 332. In addition, the "adulterated" product is subject to seizure and condemnation under Section 304 of the FDCA, 21

(continued)

This dilemma follows the product throughout the various steps of the food chain. After the product has been initially processed, it may go to a feed manufacturer for conversion to animal feed. Once again, if the substance cannot be totally removed by the processing, as if often the case, the feed manufacturer must either destroy or ship the product which may be subject to regulatory action.

The animal feed is given in turn to food-producing animals. Altnough certain environmental contaminants in animal feed are not transferred to the animal tissue, some environmental contaminants, such as the pesticide dieldrin, can be passed through to animal tissue.[3] Additionally, grazing animals may pick up contaminants directly from the pasture.

Finally, for those animals sent to slaughter, the Food Safety and Inspection Service of the United States Department of Agriculture ("USDA") conducts continuous inspection of meat and poultry products under the Poultry Products Inspection Act ("PPIA"), 21 U.S.C. §§ 451-470, and the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. §§ 601-695. If an environmental contaminant, such as dieldrin, is discovered in the animal tissue, the inspector must make the decision as to whether the meat is adulterated and should be condemned under these laws. Unfortunately, the court of appeals' decision may lead the USDA

U.S.C. § 334. Furthermore, the criminal penalty could be up to $100,000 per violation, 18 U.S.C. § 3623. Finally, if the court of appeals' decision stands, there is a great concern that because foods containing trace innocuous levels of environmental contaminants may be considered technically adulterated, unjustified product liability suits may be initiated.

[3]These foods are regulated by Section 402(a)(1) of the FDCA under the "may render injurious" standard applicable to environmental contaminants. 39 Fed. Reg. 42,743, 42,745 (Dec. 6, 1974).

inspector to conclude that, unless a formal tolerance has been established for this unavoidable contaminant, the product must be condemned and destroyed.

In sum, the court of appeals' decision leaves everyone from the seed producer to the farmer to the USDA inspector with no guidance as to what levels of an unavoidable contaminant may render a food adulterated under the FDCA, FMIA, or PPIA. At its worst, the court's decision declares that most products in the food chain are adulterated. At its best, the decision denies guidance to the agricultural industry and those who regulate it.

PROCEEDINGS BELOW

Two public interest groups and a consumer brought this suit in the United States District Court for the District of Columbia to challenge a decision of the FDA that corn containing certain levels of aflatoxin when used for certain well-defined purposes would not render the corn injurious to health. In this suit, Respondents asserted that FDA should not have proceeded as it did; rather it was mandated under Section 406 of the FDCA, 21 U.S.C. § 346, to establish formal tolerances through formal adjudicative rulemaking. The district court granted summary judgment in favor of FDA, holding that the agency has discretion on whether to proceed through informal action levels or whether it should proceed through the formal tolerance system set forth in Section 406 of the FDCA.

The court of appeals reversed, holding that FDA may not proceed by action levels rather than tolerances established through formal rulemaking procedures, pursuant to Section 701(e) of the FDCA, 21 U.S.C. § 371(e). In reaching its conclusion, the court focused first on the language of Section 406 of the FDCA, which states that a product

containing an avoidable added poisonous or deleterious substance is unsafe (and hence adulterated under Section 402(a)(2)(A) of the FDCA). For unavoidable substances, the Secretary of Health and Human Services can promulgate a formal tolerance (*i.e.*, establish a maximum amount of contaminant permitted in the product). The court read this authority as mandating formal tolerances for all unavoidable substances and then concluded that FDA could not circumvent the procedures required for establishing such tolerances (*i.e.*, formal rulemaking) through the exercise of its administrative discretion.

ARGUMENT

I. THE COURT OF APPEALS' INTERPRETATION OF THE FDCA RENDERS ALMOST ALL FOODS ADULTERATED

Both the Government and other amici have addressed the critical issue of the interplay among Sections 402(a)(1), (a)(2)(A), and 406 of the FDCA, and amici will not repeat those arguments here. But by refusing to recognize the important statutory role played by Section 402(a)(1), the court of appeals has, in essence, ruled that where the establishment of a Section 406 tolerance is technically warranted, and where no formal tolerance is in effect for a food containing an unavoidable poisonous or deleterious substance such as aflatoxin, the food is adulterated. (Pet. App.7a.)[4]

[4]This ruling contravenes the plain language of the statute. Section 406 addresses only two discrete situations. First, any poisonous or deleterious substance which is unnecessary or avoidable renders the product adulterated under Section 402(a)(2). Second, if a formal tolerance for a necessary or unavoidable contaminant is established, a product containing levels of the contaminant in excess of the tolerance is adulterated under Section 402(a)(2). Section 406 does not deal with poisonous or deleterious substances which are unavoidable and for which no tolerance is established.

The court of appeals' decision would condemn unnecessarily much of the nation's food supply, from raw agricultural commodities such as corn and cottonseed meal, to processed foods containing these products. The court of appeals' interpretation of the FDCA has created a problem where none exists, disparaging the FDA's enforcement of the FDCA and raising unwarranted fears for consumers.

II. IMPLEMENTATION OF THE COURT OF APPEALS' HOLDING IN THIS CASE WOULD BE ESPECIALLY DISRUPTIVE FOR MEAT AND POULTRY PRODUCTS AS REGULATED BY USDA

The holding of the court of appeals presents particularly serious ramifications as it relates to the regulation of meat and poultry products. USDA is primarily responsible for ensuring the safety and wholesomeness of these products and their ingredients. Yet, while reserving the right to make judgments as to the appropriateness of food substances as used in meat and poultry products, USDA generally relies upon FDA for the initial approval of food ingredients and basic determinations as to their safety. In this regard, the FMIA and PPIA, the statutes from which USDA draws its regulatory authority over meat and poultry products, and the regulations promulgated by USDA thereunder, make clear the interlocking responsibilities of USDA and FDA over food substance safety and use.

USDA has adopted informal action levels for a variety of environmental contaminants following consultation with FDA. Given the similarity in content of USDA and FDA action levels, to render nugatory the action levels informally established for environmental contaminants by FDA could render adulterated a multitude of meat and poultry products containing low levels of environmental contaminants. Invalidation of action levels may lead to the

condemnation of any meat or poultry product in which an environmental contaminant is detected.

A. The Meat and Poultry Inspection Acts Declare As Adulterated Products Containing "Poisonous or Deleterious" Substances; USDA Relies on FDA to Make Preliminary Safety Assessments for Environmental Contaminants

Like the FDCA, both the FMIA and PPIA declare as adulterated meat and poultry products that (1) bear or contain any poisonous or deleterious substance which may render them injurious to health or (2) bear or contain any added poisonous or added deleterious substance (other than one which is (a) a pesticide chemical in or on a raw agricultural commodity; (b) a food additive; or (c) a color additive) which may, in the judgment of the Secretary, make such articles unfit for human food. 21 U.S.C. §§ 601(m) and 453(g). Further, such products are rendered adulterated under those statutes if they bear or contain any food additive, color additive or, in the case of a raw agricultural commodity, pesticide chemical which is deemed unsafe within the meaning of FDCA. 21 U.S.C. §§ 601(m)(2)(B), (C), (D). The terms "pesticide chemical," "food additive," "color additive" and "raw agricultural commodity" have the same meanings for purposes of the FMIA and PPIA as they do so under the FDCA. 21 U.S.C. §§ 601(r), 453(y). Finally, both the FMIA and PPIA, like the FDCA, prohibit the sale, transport, offer for sale or transportation, or receipt for transportation in commerce of any adulterated articles. 21 U.S.C. §§ 610 (b)(1)(B), 458(a)(2)(A).

Although both the FMIA and PPIA specifically declare adulterated any meat or poultry product containing any

food additive, color additive or pesticide chemical that FDA has deemed unsafe, those statutes do not automatically declare as adulterated products containing environmental contaminants for which FDA has not established tolerances pursuant to Section 406 of the FDCA, 21 U.S.C. § 346. At least with respect to environmental contaminants, USDA retains the authority to determine on a case-by-case basis whether the presence of a contaminant renders such meat or poultry product "unfit for human food" within the meaning of the FMIA and PPIA. *See* 21 U.S.C. §§ 601(m) and 453(g). Theoretically, USDA is permitted to find a meat or poultry product containing a contaminant declared unlawful by *CNI v. Young* not to be adulterated, provided the presence of the contaminant does not, in USDA's opinion, render the product "unfit for human food."

From a practical standpoint, however, the close similarity between USDA's and FDA's "action levels" with respect to environmental contaminants – and the elimination of all "action levels" in light of the court of appeals' decision – would make USDA's decisionmaking process in this area at least chaotic and perhaps impossible.

B. Because USDA Must Inspect and Approve Every Meat and Poultry Product, It Has Virtually No Discretion to Overlook the Presence of Environmental Contaminants

Within certain limits, FDA has discretion to focus its enforcement resources by taking regulatory action against only those products containing "poisonous or deleterious" substances that present a hazard to human health. USDA, on the other hand, is under a statutory obligation to inspect and, in effect, certify as unadulterated every meat and poultry product before it may be shipped in com-

merce. The FMIA and PPIA require USDA to inspect and either affirmatively approve or prohibit shipment of all meat and poultry products prepared for commerce. 21 U.S.C. §§ 603-606, 621 and 457. Furthermore, an establishment's shipment in commerce of meat or poultry products that have not been "inspected and passed" is specifically prohibited by the FMIA and PPIA. 21 U.S.C. §§ 610(d)(2), 458(a)(2)(B).

In summary, implementation of the court of appeals' holding could disrupt the marketing of meat and poultry products more than any other foods. In establishing a continuous and mandatory inspection system under the FMIA and PPIA, Congress has unequivocally directed that USDA ensure that meat and poultry products bearing the USDA "Inspected and Passed" legend contain only those substances that have specifically been approved by FDA, unless USDA has affirmatively concluded that such substances do not render the products "unfit for human food." If FDA must establish such levels for environmental contaminants through formal rulemaking procedures, rather than informally as "action levels," any meat or poultry product containing environmental contaminants for which formal tolerances have not yet been established may not legally be approved for shipment in commerce unless and until USDA makes the independent determination that the contaminants would not adulterate the product.

In its holding the court of appeals suggested that its impact could be minimized through enforcement restraint. While this approach, as outlined by the other amici, is highly unsatisfactory, it is not a viable option for manufacturers of meat and poultry products. To the contrary, the court's ruling would either force the wholesale con-

demnation of these staples of the food supply or lead to widespread confusion and loss of public confidence in the mark of federal inspection which accompanies such products in commerce. This Court should act to avoid placing the industry, the government and consumers in such an untenable position.

CONCLUSION

For the foregoing reasons, the Petition for Writ of Certiorari should be granted.

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No. 85-664

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
Petitioner

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

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BRIEF AMICUS CURIAE OF THE GROCERY MANUFACTURERS OF AMERICA, INC. IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI AND TO SUGGEST SUMMARY REVERSAL

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BRIEF AMICUS CURIAE OF THE GROCERY MANUFACTURERS OF AMERICA, INC. IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI AND TO SUGGEST SUMMARY REVERSAL

INTEREST OF AMICUS CURIAE

The Grocery Manufacturers of America, Inc. (GMA), is a trade association representing companies that manufacture food products for nationwide distribution. Its members include the principal grocery manufacturers in this country. Members of GMA ship products in interstate commerce for

sale throughout the country and thus are subject to all of the requirements established under the Federal Food, Drug, and Cosmetic Act of 1938 (the FD&C Act)[1] relating to food safety. GMA and its members therefore have a major interest in assuring that regulatory requirements relating to food safety conform to the provisions of the FD&C Act and impose no more burdensome procedural or substantive requirements than are reasonably necessary to maintain compliance with the Act. GMA and its members strongly support the current Food and Drug Administration (FDA) approach to regulating "added poisonous or deleterious substances" in the food supply under the FD&C Act, but oppose changes that would be required by the decision of the United States Court of Appeals for the District of Columbia Circuit in this case.[2]

QUESTION PRESENTED

Does the Federal Food, Drug, and Cosmetic Act of 1938 authorize the Food and Drug Administration to determine, through exercise of its administrative discretion, whether to regulate added poisonous or deleterious substances in the food supply by (1) establishing informal "action levels" that constitute criteria for determining when the FDA will initiate court enforcement proceedings under Section 402(a)(1) of the Act, without (2) establishing formal "tolerances" through rulemaking on a record under Section 406 of the Act that constitute substantive requirements under the Act?

STATEMENT OF THE CASE

In 1906, when the first national food safety legislation was enacted,[3] Congress declared that a food was adulterated, and thus illegal, if it contained:

[1]52 Stat. 1040 (1938), 21 U.S.C. § 301 et seq.

[2]All parties have consented to the filing of this brief by letters that have been filed with the clerk of the court in accordance with Rule 36.

[3]Food and Drugs Act of 1906, 34 Stat. 768 (1906).

> ". . . any added poisonous or other added deleterious ingredient which may render such article injurious to health . . ."[4]

In construing this statutory prohibition in the *Lexington Mill* case in 1914,[5] the Supreme Court rejected both the argument made by industry on the one extreme that food could be condemned only if it was shown actually to injure health, and the argument made by the government on the other extreme that food must be condemned if it contained even a harmless amount of a substance that would be poisonous or deleterious at a higher level:

> "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of establishing, in order to secure a verdict of condemnation under this statute, that the added poisonous or deleterious substances must be such as may render such article injurious to health. The word 'may' is here used in its ordinary and usual signification, there being nothing to show the intention of Congress to affix to it any other meaning. It is, says Webster, 'an auxiliary verb qualifying the meaning of another verb, by expressing ability,. . . contingency or liability, or possibility or probability.' In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the old and the young, the well and the sick; and it is

[4]Section 7, 34 Stat. at 770.

[5]United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914).

> intended that if any flour, because of any added poisonous or other deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act."[6]

Thus, this Court took the very reasonable intermediate position that an added poisonous or deleterious substance violated the law if it represented a reasonable possibility of harm to human health under its actual conditions of use.

When Congress enacted the Federal Food, Drug, and Cosmetic Act of 1938 (the FD&C Act)[7] to replace the 1906 Act, it retained, in Section 402(a)(1), the prohibition against any "added substance" in food that is a "poisonous or deleterious substance which may render it injurious to health."[8] The legislative history makes it clear that, although this provision was slightly reworded to fit the context of the new statute, Congress intended to retain the substance of the 1906 Act provision and this Court's 1914 interpretation of the provision. The Chief of the FDA, W.G. Campbell, testified before Congress in 1934 that the language of the provision in the pending legislation that became the 1938 Act:

> ". . . is the language of the present law. That language has been considered in litigation which was carried to

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[6]*Id.* at 411. This Court has, more recently, adopted virtually an identical interpretation of the Occupational Safety and Health Act. Industrial Union Dep't, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980).

[7]52 Stat. 1040 (1938), 21 U.S.C. § 301 et seq.

[8]Section 402(a)(1) of the FD&C Act, 21 U.S.C. § 342(a)(1).

> the Supreme Court, and has been very exhaustively discussed by that Court.
>
> Now, one of the concerns that we have is, first, the most extensive and most effective protections to the public that can be made. Unquestionably the use of the subjunctive provides that. And, second, to preserve the use of language which has already been considered by the Supreme Court."[9]

The committee reports in the Senate, which exercised the lead role in this legislation, reflected this intent of the draftsmen.[10] In fact, this Court has since recognized that its 1914 decision remains the controlling construction of the 1938 Act as well:

> "The language involved in *Lexington Mill* survived generally in the Act's broadest and most general test of food adulteration, § 402(a)(1)."[11]

Thus, Congress intended that the authority of FDA to enforce the statutory prohibition against added poisonous or deleterious substances would remain the same under the 1938 Act as under the 1906 Act.

Between 1906 and 1938, however, Congress realized that not all added poisonous or deleterious substances that may render food injurious to health can or should be prohibited. Some are vitally needed to produce an adequate supply of food at reasonable cost. Accordingly, the 1938 Act included,

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[9]"Foods, Drugs, and Cosmetics," Hearings before the Committee on Commerce, United States Senate, 73d Cong., 2d Sess. 530 (1934).

[10]S. Rep. No. 493, 73d Cong., 2d Sess. 3 (1934); S. Rep. No. 361, 74th Cong., 1st Sess. 6 (1935).

[11]Flemming v. Florida Citrus Exchange, 358 U.S. 153, 161 (1958). See, e.g., United States v. 2,116 Boxes of Boned Beef, [1980-1981] Food Drug Cosm. L. Rep. (CCH) ¶ 38,114 (D. Kan. 1981).

for the first time, a provision, Section 406,[12] authorizing FDA to set tolerances for added poisonous or deleterious substances that would otherwise be banned under Section 402(a)(1) where those substances are required in the production of food or cannot be avoided by good manufacturing practice.[13] Under these circumstances, FDA was specifically given the authority to set formal tolerances, after rulemaking on a record, to establish whatever limitations are necessary for the protection of the public health. The legislative history reveals that this provision was designed to permit residues of pesticides, other added substances, and environmental contaminants.[14] This authority was intended to be in addition to, and in no way to detract from, the pre-existing prohibition against added poisonous or deleterious substances that was retained in Section 402(a)(1).

Since 1938, FDA has followed the clear intent of Congress by bringing enforcement action against added poisonous or deleterious substances under Section 402(a)(1) and, in one instance, by establishing a formal tolerance under Section 406 of the Act. To bridge these two closely-related statutory provisions, FDA has issued informal "action levels" for added poisonous or deleterious ingredients in food that serve two purposes. First, they inform the public of those levels of added poisonous or deleterious substances that do not represent a reasonable possibility of harm under actual conditions of use and thus against which enforcement is not warranted under the 1914 Supreme Court's *Lexington Mill*

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[12]21 U.S.C. § 346.

[13]For such a substance, Section 402(a)(2)(A), 21 U.S.C § 342(a)(2)(A), provides that the failure to comply with a promulgated tolerance renders the food adulterated and thus unlawful.

[14]See, e.g., S. Rep. No. 493, 73d Cong., 2d Sess. 4 (1934); S. Rep. No. 361, 74th Cong., 1st Sess. 6 (1935); and H.R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (1938).

interpretation of the safety standard in Section 402(a)(1). Second, they inform the public of the levels of added poisonous or deleterious substances that would be set at that moment under the authority of Section 406 if FDA concluded that it was a wise expenditure of scarce administrative resources to undertake a formal rulemaking proceeding to establish such tolerances. In both respects, the result is the same—FDA establishes a level of exposure that is sufficient to assure that the food does not present a reasonable possibility of harm to human health under actual conditions of use, and thus that provides a sufficient margin of safety to protect the public health.

This system has functioned smoothly for almost 50 years. The action levels currently established by FDA under this system, as contained in the official FDA publication, are reproduced in Appendix A to this brief. There is no evidence that these action levels fail adequately to protect the public health.

In 1982, however, the Community Nutrition Institute (CNI), et al., filed suit to contest the legality of this long-established interpretation and application of the law. CNI sought to require FDA to establish a formal tolerance under Section 406, through rulemaking on a record, for every added poisonous or deleterious substance in the food supply. After the district court rejected CNI's position, the court of appeals upheld it.[15] The Solicitor General has petitioned for a writ of certiorari. This brief amicus curiae is submitted in support of the petition, and to suggest that the Court summarily reverse the decision of the court of appeals on the basis that it conflicts with two controlling Supreme Court precedents.

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[15]Community Nutrition Institute v. Young, 757 F.2d 354 (D.C. Cir. 1985).

REASONS FOR GRANTING THE PETITION

The decision of the court of appeals—which would overturn FDA's long-established administrative interpretation of the law, impose in its place an unreasonable and burdensome new regulatory scheme that will not increase public health protection, conflict with two authoritative Supreme Court decisions, and render the vast bulk of the American food supply unlawful for the foreseeable future—is clearly incorrect. This Court should therefore grant the petition for a writ of certiorari and summarily reverse the court of appeals.

I. The Food Supply Unavoidably Contains Hundreds of "Added Poisonous or Deleterious Substances" at Trace Levels That Do Not Represent a Reasonable Possibility of Harm to Human Health Under Actual Conditions of Use.

Throughout history, the food supply has always contained trace amounts of substances that are unavoidably added in the course of food production and processing. As part of the industrial revolution, our large urban centers developed, and people no longer grew their own food. Dramatic changes were needed in food production, transportation, processing, packaging, and preservation in order to accommodate this new national lifestyle. Society increasingly depended upon chemicals of both natural and synthetic origin to serve these purposes, and the number and frequency of trace amounts of these substances in the food supply therefore inevitably increased.

Although these unavoidable added substances have always been present, they have not always been detectable by the scientific methodology available to analytical chemists. At the beginning of this century, for example, when the 1906 Act was enacted, analytical methodology was basically qualitative rather than quantitative in nature and in some

respects had advanced very little beyond what was known and practiced in ancient Greece and Rome.[16] By the time that the 1938 Act was passed, analytical methodology had become more quantitative in nature, but was accurate only at relatively high levels. When the Food Additives Amendment of 1958[17] was enacted, the sensitivity of detection methodology had been reduced to the relatively high parts per million (ppm) level. During the past 30 years, it has progressively been reduced first to the very low ppm level, then to parts per billion (ppb) and parts per trillion (ppt), and now to parts per quadrillion (ppq).[18] In a preamble to a proposed regulation published by FDA in 1979, the agency described this:

> ". . . trend of the increasing capacity of analytical chemistry to detect [and] measure the presence of chemicals. Depending on the substance or class of substances, this decrease in the lowest limits of measurement during the last 20 years ranges between two and five orders of magnitude [i.e., between 100 and 100,000 times]."[19]

It is helpful, in appreciating the significance of these levels, to realize that one ppb, which is now commonplace for all

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[16]Browne, Adulteration and the Condition of Analytical Chemistry Among the Ancients, 29 Science 455 (March 19, 1909). Dr. Browne served as President of the Association of Official Analytical Chemists in 1925 and as Commissioner of Food and Drugs during 1923-1927.

[17]72 Stat. 1784 (1958).

[18]E.g., Richardson et al., Sub-Part-Per-Trillion Detection of Riboflavin by Laser-Induced Fluorescence, 86 Analytica Chimica Acta 263 (1976).

[19]44 Fed. Reg. 17070, 17075 (March 20, 1979). The notice included tables showing the increased sensitivity of the analytical detection methodology for specific chemicals. Id. at 17076-17077.

detection methodology, is equivalent to one second in 32 years or one inch in 16,000 miles.

With every incremental advance in the science of analytical chemistry, more and more added substances have been found at trace levels in the American food supply. Most, if not all, of these added substances would be regarded as "poisonous or deleterious" at higher levels of use, but pose no reasonable possibility of harm to human health under their actual conditions of use. Poisonous or deleterious substances that could not be found at the ppm level can often be found at the ppb or ppt level, and are even more certain to be found at the ppq level. Although it appeared in 1938, when Section 406 was enacted, that there were relatively few unavoidable poisonous or deleterious substances to be found in food, it is now apparent that there are literally hundreds of them.

Were it not for the statutory interpretation of the food safety provisions of the FD&C Act adopted and consistently applied by FDA, this would have become a regulatory nightmare both for FDA and for the food industry. As more and more poisonous or deleterious substances are found at low levels, decisions must be made by FDA on how best to handle them in order to assure a safe food supply for the American public.

Under the FDA regulatory approach that has prevailed for the past half century, this has proved to be a manageable task. For those trace poisonous or deleterious substances that represent a trivial risk, FDA simply ignores their presence and does not establish either an informal action level or a formal tolerance. For those that are found at levels that could potentially approach amounts of public health concern, action levels (shown in Appendix A) have been established to make certain that they represent no reasonable possibility of harm to human health. As more has become known about those substances (and their toxicity and level of human exposure), those action levels have been changed over time. In the one instance where sufficient data have accumulated to permit a permanent maximum level, and persistent litigation justified the time and expense involved in the administrative proceeding, a formal tolerance has been promulgated on the basis of a rulemaking on a record.[20]

This approach is sensible and has in fact worked very well to protect the health of the American public. FDA has established conservative levels for added poisonous or deleterious substances and in fact no human toxicity has been traced to them.

II. The Decision of the Court of Appeals Would Impose a Burdensome and Unreasonable Regulatory Scheme Without Any Public Health Benefit.

In place of the existing common sense approach that has prevailed for the past 50 years, the court of appeals would arbitrarily require an expensive and time-consuming new scheme that would serve no public health purpose. The novel interpretation advanced by the court of appeals would require the formal establishment of a tolerance under Section 406, based upon rulemaking on a record, for every poisonous or deleterious substance found in the food supply. At the outset, this would encompass all of the substances, and all of the uses specified, in the current FDA action levels reprinted in Appendix A.

This would, however, only be the beginning. Many of the poisonous or deleterious substances listed in Appendix A can readily be found, under modern methods of analytical

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[20] 21 C.F.R. § 109.30 (polychlorinated biphenyls).

chemistry, in other foods as well. And as analytical methods become increasingly more sensitive, they will be found in still other food products.

Nor would this be the end of the matter. There are hundreds of poisonous or deleterious substances presently found in the food supply, under extremely sensitive detection methodology, which present such a trivial risk that FDA has not bothered to list them or to establish an action level. Under the extreme interpretation of the court of appeals, however, FDA would be required to establish a formal tolerance even for these substances, to avoid the food becoming unlawful per se.

All of this would be required solely in the name of strict statutory construction, with no attention paid to the overall statutory structure or to the protection of the public health. Scarce agency and industry resources would be channeled away from productive enterprise into formal rulemaking proceedings designed solely to satisfy procedural requirements. Formal rulemaking on a record, which is subject to the strict requirements for adjudication under the Administrative Procedure Act,[21] is resource-intensive and imposes substantial burdens upon FDA and the regulated industry.[22] There has been, and can be, no suggestion that any of these proceedings would advance public health objectives.

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[21]5 U.S.C. § 556 and § 557.

[22]See, e.g. Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 Tex. L. Rev. 1132 (1972). The enormous administrative burden that would have been imposed by the requirement of hundreds of such formal administrative hearings was one factor that led this Court to conclude that the FD&C Act should not be interpreted to incorporate such a requirement for all new drug application withdrawals in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 621 (1973).

To the extent that any person believes that a current FDA action level is too high (or too low), or that a poisonous or deleterious substance found at trace levels that represent only a trivial risk should be regulated through an action level, procedural remedies are presently available. FDA has promulgated regulations establishing the right of any person to petition FDA for appropriate action under these circumstances.[23] There is no need to establish an entire new regulatory scheme in order to assure adequate protection both of the procedural rights of interested persons and of the substantive right to a safe food supply.

III. The Decision of the Court of Appeals Conflicts With Two Authoritative Supreme Court Decisions.

The decision of the court of appeals in this case is fundamentally in conflict with two major Supreme Court decisions, one of which was decided less than a week before the decision in this case.

A. The *Lexington Mill* Decision Establishes FDA's Court Enforcement Authority Under Section 402(a)(1).

As noted above, the prohibition against added poisonous or deleterious substances under the 1906 Act, as interpreted by this Court in the *Lexington Mill* case in 1914, was explicitly retained by Congress under the 1938 Act.[24] Thus, Congress intended FDA to continue to exercise its administrative enforcement discretion to determine whether it was reasonably possible that an added poisonous or deleterious substance would render food injurious to health under actual conditions of use. There is no legislative history to support the view, advanced by the court of appeals, that

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[23]21 C.F.R. § 109.5 and § 10.30.

[24]Notes 9-11 *supra* and accompanying text.

enactment of Section 406 qualified or overruled this independent court enforcement authority.

This Court has, in an analogous context, recognized that FDA has been given two independent methods of enforcing a common statutory objective—administrative rulemaking proceedings and direct action in the courts. In the Bentex[25] andCIBA[26] cases, the Court held that FDA has primary jurisdiction to decide with administrative finality the regulatory status of products within its jurisdiction and, at the same time, independently has administrative discretion to initiate enforcement action directly in the courts. The CIBA decision explicitly recognized the power of FDA to initiate court enforcement action without first undertaking an administrative proceeding. The same logic applies here as well. Thus, the provisions of Section 406, relating to administrative proceedings, should in no way interfere with the provisions of Section 402(a)(1) authorizing court enforcement proceedings.

B. The Decision in Heckler v. Chaney Establishes That An FDA Administrative Determination Not To Initiate Court Enforcement Action Is Ordinarily Unreviewable In The Courts.

Just six days after the court of appeals handed down its decision in the instant case, the Supreme Court handed down its decision in *Heckler v. Chaney*.[27] It is apparent that the decision of the court of appeals is in serious conflict with the *Chaney* decision.

In *Chaney*, the Court held that an FDA decision not to initiate court enforcement action is ordinarily unreviewable

[25]Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973).

[26]CIBA Corp. v. Weinberger, 412 U.S. 640, 643-644 (1973).

[27]Heckler v. Chaney, 105 S. Ct. 1649 (1985).

in the courts. Absent fraud or other extraordinary circumstances, enforcement decisions are "committed to agency discretion" under the Administrative Procedure Act. The Court explained some of the "administrative concerns" which underlie this policy:

> "First, an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities. Similar concerns animate the principles of administrative law that courts generally will defer to an agency's construction of the statute it is charged with implementing, and to the procedures it adopts for implementing that statute."[28]

These "administrative concerns" describe, of course, the very reasons why FDA enforcement of the food safety provisions of the law must remain within the scope of administrative discretion.

The decision of the court of appeals, however, takes the matter entirely out of FDA's administrative discretion and requires the agency to establish formal tolerances, through

[28]Id. at 1656.

rulemaking on a record, for each and every poisonous or deleterious substance found in the food supply. Under the interpretation adopted by the court of appeals, FDA's deployment of resources, and ordering of priorities, would be dictated by procedures imposed by the judiciary and not by public health concerns. They would be required for purely procedural rather than substantive reasons. The approach adopted by the court of appeals is thus irreconcilable with the approach of this Court in *Chaney*.

Even if formal tolerances were adopted for all poisonous or deleterious substances under Section 406, the *Chaney* decision—handed down just a few days before the decision in the instant case, and clearly not considered by the court of appeals in arriving at its own decision—would make them a procedural nicety and a substantive nullity. Enforcement priorities would remain discretionary with FDA regardless of the procedure imposed upon FDA in establishing unacceptable levels of poisonous or deleterious substances in the food supply. It makes little sense to reorder FDA's priorities, and to abrogate a well-established food safety regulatory program that has stood the test of 50 years of experience, when the end result will be no different than it is now.

IV. The Decision of the Court of Appeals Would Automatically Render the Vast Bulk of the American Food Supply Unlawful for the Foreseeable Future.

The action levels that would be invalidated by the court of appeals, as shown in Appendix A, pertain to a substantial portion of this country's food supply. Under the novel interpretation adopted by the court of appeals, all of the food covered by those action levels would instantly become adulterated and thus illegal per se under the FD&C Act. Equally important, all other foods which contain added poisonous or deleterious substances that FDA has determined to present only a trivial risk, and thus do not justify even an action level, would be equally unlawful. With the extraordinary sensitivity of detection methodology now available to analytical chemists, it is difficult to imagine many foods, if any, that would escape this broad condemnation.

Even with heroic efforts and the deployment of a substantial portion of FDA personnel, it is unlikely that administrative proceedings could be initiated and completed for all of these added poisonous or deleterious substances in all of the myriad foods that comprise our national diet.[29] It is likely that, as soon as one proceeding was completed, other added poisonous or deleterious substances would be detected in still other foods. It is thus questionable whether FDA could ever catch up with the problem, or would forever be chasing an unachievable administrative goal.

This regulatory dilemma only serves to underscore the impractical and unrealistic interpretation adopted by the court of appeals, and the sound policy reasons for the consistent administrative interpretation adopted by FDA of these provisions for the past 50 years. As this Court has recognized, the FD&C Act "is to be treated as a working instrument of government and not merely as a collection of English words"[30] and thus must be given "a liberal construction consistent with the Act's overriding purpose to protect the public health."[31] Formalistic requirement of rigid Section 406 tolerances, after rulemaking on a record, will achieve no such purpose.

It is no comfort to the food industry that, under the *Chaney* decision, FDA undoubtedly would exercise its in-

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[29]Note 22 *supra*.

[30]United States v. Dotterweich, 320 U.S. 277, 280 (1943).

[31]United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969).

herent administrative discretion not to initiate court enforcement action against the entire food supply or even those foods for which action levels have been established as shown in Appendix A. There are serious commercial implications that could flow from the decision of the court of appeals as well. Under the Uniform Commercial Code, all food is sold subject to the implied warranties of merchantability and fitness for the intended purpose.[32] Food that is in violation of federal law could readily be regarded as in violation of this implied warranty. Accordingly, the decision by the court of appeals could jeopardize virtually all commercial transactions in the food industry. Those who sought a way to abrogate contracts for the sale of food need look no further than the decision of the court of appeals in the instant case.

V. This Court Should Summarily Reverse the Decision of the Court of Appeals on the Basis of Lexington Mill and Heckler v. Chaney.

As demonstrated in Part III of this brief, the decision of the court of appeals contradicts the decisions of this Court in *Lexington Mill* and *Heckler v. Chaney*. The decision in *Heckler v. Chaney*, moreover, preceded the decision in the instant case by only six days and thus clearly was not considered by the court of appeals. Accordingly, this Court should summarily reverse the court of appeals, without the need for further briefing or oral argument, on the basis of those two controlling precedents.

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[32]Uniform Commercial Code § 2-314 and § 2-315.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted and the decision of the court of appeals should summarily be reversed.

Respectfully submitted,

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APPENDIX A

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

Action levels for poisonous or deleterious substances are established by the Food and Drug Administration (FDA) to control levels of contaminants in human food and animal feed.

The action levels are established and revised according to criteria specified in Title 21, *Code of Federal Regulations*, Parts 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective.

Action levels and tolerances represent limits at or above which FDA will take legal action to remove adulterated products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant.

Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable. The blending of a food or feed containing a substance in excess of an action level or tolerance with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

This booklet lists action levels established by the FDA for poisonous or deleterious substances in human food and animal feed. This list is current as of September, 1982. Notices will be published in the *Federal Register* as new action levels are established or as existing action levels are revised or revoked. It is the responsibility of the user of the list to keep up to date on changes in the action levels.

Single *copies* of this booklet are available from:

Food and Drug Administration
Industry Programs Branch
Bureau of Foods (HFF-326)
200 C Street, S.W.
Washington, D.C. 20204
Phone (202) 245-1523

Copies of the *Compliance Policy Guides* (CPG) referenced in the action level list may be obtained from:

Food and Drug Administration
Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857
Phone (301) 443-6310

Other *references* in the action level list are filed under Docket No. 77N-0166 for public viewing at:

Food and Drug Administration
Docket's Management Branch (HFA-305)
5600 Fishers Lane
Rockville, Maryland 20857
Phone (301) 443-1753

For further *assistance or information* contact:

Food and Drug Administration
Guidelines and Compliance Research Branch
Bureau of Foods (HFF-312)
200 C Street, S.W.
Washington, D.C. 20204
Phone (202) 245-3092

FDA ACTION LEVELS
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FDA ACTION LEVELS

AFLATOXIN

Commodity	Action Level	Reference
Brazil nuts	20.0 mcgs/kg	CPG 7112.07
Feeds and feed ingredients	20.0 ppb	CPG 7126.33
Foods	20.0 mcgs/kg	CPG 7120.26
Milk	0.5 ppb (aflatoxin M_1)	CPG 7106.10
Peanuts & peanut products	20.0 mcgs/kg	CPG 7112.02
Pistachio nuts	20.0 mcgs/kg	CPG 7112.08

ALDRIN & DIELDRIN

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at a level below 0.03 ppm for nonfatty foods and 0.3 ppm for fish and for milk.

Commodity	Action Level	Reference
Animal feed, finished, processed	0.03 ppm	CPG 7126.27-A
Artichokes	0.05 ppm	CPG 7120.23-A
Eggs	0.03 ppm	CPG 7120.23-A
Fats & oils: animal, vegetable fish (animal feed)	0.3 ppm	CPG 7126.27-A
Fish and shellfish	0.3 ppm	CPG 7120.23-A
Figs	0.05 ppm	CPG 7120.23-A
Hay (animal feed)	0.03 ppm	CPG 7126.27-A

Melons[1]	0.15 ppm	CPG 7120.23-A
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-A
Small fruits[1,2]	0.05 ppm	CPG 7120.23-A
Sugarbeet pulp (animal feed)	0.1 ppm	CPG 7126.27-A

[1]Other than those commodities specified in 40 C.F.R 180.135 and 180.137.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

BENZENE HEXACHLORIDE (BHC)

The figures below are for residues of total BHC. However, in adding amounts of individual isomers do not count alpha, gamma or delta BHC at a level below 0.1 ppm in milk or eggs and below 0.02 in other products. Do not count beta BHC at a level below 0.2 in milk or eggs and below 0.04 in other products.

Commodity	Action Level	Reference
Animal feed, processed	0.1 ppm	CPG 7126.27-B
Barley, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Barley, grain (human food)	0.1 ppm	CPG 7120.23-B
Beans	0.5 ppm	CPG 7120.23-B
Citrus fruit[2]	0.5 ppm	CPG 7120.23-B
Cocoa beans, whole raw bean	0.5 ppm	CPG 7120.23-B
Corn, fresh sweet	0.5 ppm	CPG 7120.23-B
Corn, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Corn, grain (human food)	0.1 ppm	CPG 7120.23-B
Eggs	0.5 ppm	CPG 7120.23-B
Endive	0.5 ppm	CPG 7120.23-B
Figs	0.5 ppm	CPG 7120.23-B
Frog legs	0.5 ppm	CPG 7120.23-B
Guavas	0.5 ppm	CPG 7120.23-B
Hays (animal feed)	0.1 ppm	CPG 7126.27-B
Mangoes	0.5 ppm	CPG 7120.23-B
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-B
Milo, sorghums (animal feed)	0.1 ppm	CPG 7126.27-B
Milo, sorghums (human food)	0.1 ppm	CPG 7120.23-B
Oats, grain (animal feed)	0.1 ppm	CPG 7126.27-B

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Oats, grain (human food)	0.1 ppm	CPG 7120.23-B
Peas	0.5 ppm	CPG 7120.23-B
Pineapples	0.5 ppm	CPG 7120.23-B
Quinces	0.5 ppm	CPG 7120.23-B
Root vegetables[2]	0.5 ppm	CPG 7120.23-B
Rice, grain	0.1 ppm	CPG 7120.23-B
Rye, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Rye, grain (human food)	0.1 ppm	CPG 7120.23-B
Small fruits[1],[2]	0.5 ppm	CPG 7120.23-B
Turnip greens	0.5 ppm	CPG 7120.23-B
Wheat, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Wheat, grain (human food)	0.1 ppm	CPG 7120.23-B

[1]Other than those commodities specified in 40 C.F.R. 180.146.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

CADMIUM

Commodity	Action Level	Reference
Pottery(ceramics)		CPG 7117.06
Flatware (ave. of 6 units)	0.5 mcgs/ml of leaching solution	
Small hollowware (any one of 6 units)	0.5 mcgs/ml of leaching solution	CPG 7117.06
Large hollowware (any one of 6 units)	0.25 mcgs/ml of leaching solution	CPG 7117.06

CHLORDANE

Commodity	Action Level	Reference
Animal fat, rendered	0.8 ppm	CPG 7126.27-C
Animal feed	0.1 ppm	CPG 7126.27-C
Fish	0.3 ppm	CPG 7120.23-C

CROTALARIA SEEDS
(C. spectabilis and/or C. sagittalis and/or C. striata)

Commodity	Action Level	Reference
Grains and Feeds	Average of 1 whole seed/pound	CPG 7126.15

FDA ACTION LEVELS

DIBROMOCHLOROPROPANE (DBCP)

Commodity	Action Level	Reference
Milk	1.5 ppm (fat basis)	CPG 7120.23-E
Raw agricultural commodities (except milk)	0.05 ppm	CPG 7120.23-E

DDT, DDE, AND TDE

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of DDT, DDE and TDE do not count any of the three found below 0.2 ppm for fish, eggs, and grain.

Commodity	Action Level	Reference
Animal feed, processed	0.5 ppm	CPG 7126.27-D
Barley, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Barley, grain (human food)	0.5 ppm	CPG 7120.23-D
Cocoa beans, whole raw bean	2.0 ppm	CPG 7120.23-D
Corn, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Corn, grain (human food)	0.5 ppm	CPG 7120.23-D
Eggs	1.5 ppm	CPG 7120.23-D
Fish	5.0 ppm	CPG 7120.23-D
Hay	0.5 ppm	CPG 7126.27-D
Milo (sorghum), grain (animal feed)	0.5 ppm	CPG 7126.27-D
Milo (sorghum), grain (human food)	0.5 ppm	CPG 7120.23-D
Oats, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Oats, grain (human food)	0.5 ppm	CPG 7120.23-D
Rice, grain (animal feed)	0.5 ppm	CPG 7126.27-D

Rice, grain (human food)	0.5 ppm	CPG 7120.23-D
Rye, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Rye, grain (human food)	0.5 ppm	CPG 7120.23-D
Wheat, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Wheat, grain (human food)	0.5 ppm	CPG 7120.23-D

FDA ACTION LEVELS

ENDRIN

Commodity	Action Level	Reference
Animal feed, processed	0.03 ppm	CPG 7126.27-E
Asparagus	0.05 ppm	CPG 7120.23-F
Beans	0.05 ppm	CPG 7120.23-F
Citrus fruits[2]	0.05 ppm	CPG 7120.23-F
Corn, fresh sweet	0.05 ppm	CPG 7120.23-F
Eggs	0.03 ppm	CPG 7120.23-F
Figs	0.05 ppm	CPG 7120.23-F
Fish and shellfish	0.3 ppm	CPG 7120.23-F
Fish meal, fish solubles, fish oil (animal feed)	0.3 ppm	CPG 7126.27-E
Guavas	0.05 ppm	CPG 7120.23-F
Leafy vegetables[1],[2]	0.05 ppm	CPG 7120.23-F
Mangoes	0.05 ppm	CPG 7120.23-F
Melons	0.05 ppm	CPG 7120.23-F
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-F
Oilseed meal-peanut, soybean, cottonseed, etc. (animal feed)	0.03 ppm	CPG 7126.27-E
Okra	0.05 ppm	CPG 7120.23-F
Peas	0.05 ppm	CPG 7120.23-F
Pimentoes	0.05 ppm	CPG 7120.23-F
Pineapples	0.05 ppm	CPG 7120.23-F
Pome fruits[2]	0.05 ppm	CPG 7120.23-F
Pumpkins	0.05 ppm	CPG 7120.23-F
Root vegetables[1],[2]	0.05 ppm	CPG 7120.23-F
Small fruits[2]	0.05 ppm	CPG 7120.23-F
Stone fruits[2]	0.05 ppm	CPG 7120.23-F

[1]Other than those commodities specified in 40 C.F.R. 180.131.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Vegetable oils and fats, including soapstock (animal feed)	0.3 ppm	CPG 7126.27-E

FDA ACTION LEVELS

FENTHION

Commodity	Action Level	Reference
Ground red peppers	0.3 ppm	CPG 7120.23-G

FDA ACTION LEVELS

HEPTACHLOR AND HEPTACHLOR EPOXIDE

The figures below are for residues of the above pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found at a level below 0.3 ppm for fish and 0.03 ppm for other products.

Commodity	Action Level	Reference
Animal feed, processed	0.03 ppm	CPG 7126.27-F
Artichokes	0.05 ppm	CPG 7120.23-H
Asparagus	0.05 ppm	CPG 7120.23-H
Beans, except snap beans	0.05 ppm	CPG 7120.23-H
Citrus fruits[2]	0.05 ppm	CPG 7120.23-H
Cucumbers	0.05 ppm	CPG 7120.23-H
Dairy products (manufactured)[1]	0.1 ppm	CPG 7120.23-H
Eggs	0.03 ppm	CPG 7120.23-H
Eggplant	0.05 ppm	CPG 7120.23-H
Figs	0.05 ppm	CPG 7120.23-H
Fish and shellfish	0.3 ppm	CPG 7120.23-H
Leafy vegetables	0.05 ppm	CPG 7120.23-H
Hays[1]	0.03 ppm	CPG 7126.27-F
Melons	0.05 ppm	CPG 7120.23-H
Okra	0.05 ppm	CPG 7120.23-H
Pears	0.05 ppm	CPG 7120.23-H
Pimentoes	0.05 ppm	CPG 7120.23-H
Pumpkins	0.05 ppm	CPG 7120.23-H
Quinces	0.05 ppm	CPG 7120.23-H
Rice, grain, (animal feed)	0.03 ppm	CPG 7126.27-F
Rice, grain (human food)	0.03 ppm	CPG 7120.23-H
Small fruits[1],[2]	0.05 ppm	CPG 7120.23-H

[1]Other than those commodities specified in 40 C.F.R. 180.104 and 180.319.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Stone fruits[1],[2]	0.05 ppm	CPG 7120.23-H
Squash (summer or winter)	0.05 ppm	CPG 7120.23-H

[1]Other than those commodities specified in 40 C.F.R. 180.104 and 180.319.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

KELTHANE
[1,1 Bis (p-chlorophenyl)-2,2,2-trichloroethanol]

Commodity	Action Level	Reference
Animal feed, finished processed	0.5 ppm	CPG 7126.27-H

KEPONE
[Decachlorooctahydro-1,3,4-methano-2H-cyclobuta (cd) pentalen-2-one]

Commodity	Action Level	Reference
Crabmeat	0.4 ppm	CPG 7120.23-I
Fish	0.3 ppm	CPG 7120.23-I
Shellfish	0.3 ppm	CPG 7120.23-I

FDA ACTION LEVELS

LEAD

Commodity	Action Level	Reference
Pottery (ceramics)		CPG 7117.07
Flatware (ave. of 6 units)	7.0 mcgs/ml of leaching solution	
Small hollowware (any one of 6 units)	5.0 mcgs/ml of leaching solution	CPG 7117.07
Large hollowware (any one of 6 units)	2.5 mcgs/ml of leaching solution	CPG 7117.07
Silver-plated hollowware (ave. of 6 units)	7.0 mcgs/ml of leaching solution if product intended for use by adults	CPG 7117.05
Silver-plated hollowware (one or more of 6 units)	0.5 mcgs/ml of leaching solution if product intended for use by infants and children	CPG 7117.05

FDA ACTION LEVELS

LINDANE

Commodity	Action Level	Reference
Animal feed, processed	0.1 ppm	CPG 7126.27-H
Artichokes	0.5 ppm	CPG 7120.23-J
Barley, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Barley (human food)	0.1 ppm	CPG 7120.23-J
Beans	0.5 ppm	CPG 7120.23-J
Citrus fruit[2]	0.5 ppm	CPG 7120.23-J
Cocoa beans, whole raw bean	0.5 ppm	CPG 7120.23-J
Corn, fresh sweet	0.5 ppm	CPG 7120.23-J
Corn, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Corn, grain (human food)	0.1 ppm	CPG 7120.23-J
Eggs	0.5 ppm	CPG 7120.23-J
Endive	0.5 ppm	CPG 7120.23-J
Figs	0.5 ppm	CPG 7120.23-J
Hays	0.1 ppm	CPG 7126.27-H
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-J
Milo (sorghum), grain (animal feed)	0.1 ppm	CPG 7126.27-H
Milo (sorghum), grain, (human food)	0.1 ppm	CPG 7120.23-J
Oats, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Oats, grain (human food)	0.1 ppm	CPG 7120.23-J
Peas	0.5 ppm	CPG 7120.23-J
Rice, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Rice, grain (human food)	0.1 ppm	CPC 7120.23-J
Root vegetables[1],[2]	0.5 ppm	CPG 7120.23-J
Rye, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Rye, grain (human food)	0.1 ppm	CPG 7120.23-J

[1]Other than those commodities specified in 40 C.F.R. 180.133.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Small fruits[1],[2]	0.5 ppm	CPG 7120.23-J
Turnip greens	0.5 ppm	CPG 7120.23-J
Wheat, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Wheat, grain (human food)	0.1 ppm	CPG 7120.23-J

[1]Other than those commodities specified in 40 C.F.R. 180.133.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

MERCURY

Commodity	Action Level	Reference
Fish, shellfish, crustaceans, other aquatic animals. Edible portion only. Fresh, frozen or processed.	1.0 ppm	CPG 7108.07
Wheat (pink kernals only)	1.0 ppm	CPG 7104.05

METHYL ALCOHOL

Commodity	Action Level	Reference
Imported brandy	0.35%	CPG 7119.09

MIREX

Commodity	Action Level	Reference
Fish	0.1 ppm	CPG 7120.23-K

NITROSODIMETHYLAMINE (NDMA)

Commodity	Action Level	Reference
Barley Malt	10 ppb	CPG 7104.07
Malt Beverages	5 ppb	CPG 7101.07

FDA ACTION LEVELS

PARALYTIC SHELLFISH TOXIN

Commodity	Action Level	Reference
Clams (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20
Mussels (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20
Oysters (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20

POLYBROMINATED BIPHENYLS (PBB's)

Commodity	Action Level	Reference
Milk & dairy products (fat basis)	0.3 ppm	"A Review of Congressman William M. Brodhead's Petition to Reduce FDA Action Levels for Polybrominated Biphenyls (PBB) in Food", July 27, 1977
Meat (fat basis)	0.3 ppm	
Eggs	0.05 ppm	
Animal Feed	0.05 ppm	

FDA ACTION LEVELS

POLYCHLORINATED BIPHENYLS (PCB's)

Commodity	Action Level	Reference
Paper food-packaging material intended for or used with human food, finished animal feed and components intended for animal feeds	10 ppm	21 CFR 109.30 (a)(9) and 509.30 (a)(9) Tolerance stayed on 8-24-73 (38 FR 22794) 21 CFR 109.6(d) and 509.6(d)
Red Meat	3 ppm (fat basis)	CPG 7111.03

TOXAPHENE

Commodity	Action Level	Reference
Animal feed, processed	0.5 ppm	CPG 7126.27-I
Artichokes	1.0 ppm	CPG 7120.23-L
Asparagus	1.0 ppm	CPG 7120.23-L
Cherries	1.0 ppm	CPG 7120.23-L
Figs	1.0 ppm	CPG 7120.23-L
Fish	5.0 ppm	CPG 7120.23-L
Melons	1.0 ppm	CPG 7120.23-L
Mustard greens	1.0 ppm	CPG 7120.23-L
Plums	1.0 ppm	CPG 7120.23-L
Pumpkins	1.0 ppm	CPG 7120.23-L
Root vegetables[1],[2]	1.0 ppm	CPG 7120.23-L
Small fruits[1],[2]	1.0 ppm	CPG 7120.23-L

[1]Other than those commodities specified in 40 C.F.R. 180.138.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Squash (summer or winter)	1.0 ppm	CPG 7120.23-L
Turnip greens	1.0 ppm	CPG 7120.23-L

Supreme Court, U.S.
FILED
FEB 10 1986
JOSEPH F. SPANIOL, JR.
CLERK

Nos. 85-664

In the Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

JOINT APPENDIX

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PETITION FOR A WRIT OF CERTIORARI FILED OCTOBER 18, 1985
CERTIORARI GRANTED DECEMBER 9, 1985

In the Supreme Court of the United States

OCTOBER TERM, 1985

No. 85-664

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS, PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 84-5223

(Civil Action No. 80-03110)

COMMUNITY NUTRITION INSTITUTE, ET AL.
APPELLANTS

v.

FRANK YOUNG, COMMISSIONER
FOOD AND DRUG ADMINISTRATION

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

RELEVANT DOCKET ENTRIES

Date	Filings – Proceedings
(B)04-13-84	Copy of notice of appeal and docket entries from Clerk, DC (n-4)
(B)04-13-84	Docketing fee was paid in the District Court on 04-11-84
(B)04-13-84	Docketing statement was mailed to counsel for appellants
(J)05-03-84	4 – Appellants' docketing statement (m-2)
(B)05-10-84	Clerk's order that a briefing schedule is set as follows: Appellants' brief and appendix (or record excerpts of Gen. Rule 17(c) transcripts) – 07-02-84: Appellee's brief – 08-01-84: Appellants' reply brief, if any – 08-15-84. Based upon the foregoing schedule, the Clerk shall include this case in the pool of cases available for selection on this Court's Nov./Dec., 1984 calendar.

(J)07-02-84	15 – Appellants' brief (m-2) (p-2)
(J)07-02-84	7 – Joint appendix (m-2) (p-2)
(J)07-27-84	4 – Appellee's motion for leave to file motion to extend time to file brief (m-27)
(V)08-01-84	Clerk's order that the motion, leave to file the instant motion is hereby granted, to extend briefing time is granted; and the briefing schedule is revised as follows: Appellee(s) brief – 08/22/84; Appellant(s) reply brief – 09/05/84. This disposition will not affect the calendaring of the instant case
(V)08-01-84	4 – Motion for extension of time to file appellee's brief (m-27) – per above order
(C)08-22-84	4 – Appellees' motion for leave to file motion to extend time to file brief (m-22)
(V)08-24-84	Clerk's order that the motion to extend briefing time is granted; and the briefing schedule is revised as follows: Appellee(s) brief – 08/29/84; Appellant(s) reply brief – 09/12/84. This disposition will not affect the calendaring of the instant case (Leave to file the instant motion is hereby granted)
(V)08-24-84	4 – Motion for extension of time to file appellee's brief (m-22) – per above order
(J)08-29-84	4 – Appellees' motion for leave to file brief in xerox form pending printing (m-29)
(J)08-29-84	1 – Notice of consent from parties to the filing of amicus curiae brief of the State of South Carolina
(J)08-29-84	15 – Brief of State of South Carolina as amicus curiae (m-29)
(V)09-05-84	Clerk's order granting appellee's motion for leave to file brief temporarily in photocopy form

(V)09-05-84	4 – Appellee's brief (m-29)
(J)09-11-84	4 – Appellants' motion for leave to file motion to extend time to file reply brief (m-11)
(J)09-25-84	15 – Appellee's brief (m-25)
(J)09-26-84	15 – Appellants' brief
(V)10-15-84	Clerk's order that the motion, leave to file the motion is hereby granted, to extend briefing time is granted; and the briefing schedule is revised as follows Appellant(s) reply brief – 10/15/84. This disposition will not affect the calendaring of the instant case. The Clerk shall retain the instant case in the pool of cases available for selection on this Court's November/December calendar
(V)10-15-84	4 – Motion for extension of time to file reply brief (m-11) – per above order
(V)10-15-84	15 – Appellants' reply brief (m-24)
(C)01-05-84 [sic]	CERTIFIED ORIGINAL RECORD (1 vol.)
(V)01-15-85	Clerk's order, sua sponte, that the following times are alloted for oral agrument Appellants – 25 minutes; Appellee – 25 minutes
(F)01-25-85	Argued before Mikva, Edwards, and Starr, CJs
(D)03-26-85	Opinion for the Court filed by Circuit Judge Starr.
(D)03-26-85	Judgment by this Court that the judgment of the District Court appealed from in this cause is hereby vacated and this case is remanded for further consideration, all in accordance with the Opinion for the Court filed herein this date.
(D)03-26-85	Mandate order.

(R)04-26-85	4—Appellant's motion to file bill of cost (m-24) [9]
(D)05-01-85	Per Curiam order, sua sponte, that the Opinion for the Court filed by Circuit Judge Starr on March 26, 1985 be, and hereby is amended. (SEE ORDER FOR DETAILS).
(R)05-10-85	15—Appellee's petition for rehearing and suggestion for rehearing en banc (m-10) [1]
(E)05-23-85	Per curiam order that appellee's petition for rehearing is denied. Mikva, Edwards and Starr, CJs.
(T)05-23-85	Per Curiam order, en banc, denying the suggestion for rehearing en banc; CJ Robinson, Wright, Tamm, Wald, Mikva, Edwards, Ginsburg, Bork, Scalia and Starr, CJs
(D)06-07-85	MANDATE ISSUED. Costs to be determined at a later date.
(E)06-13-85	Per curiam order denying appellants' motion to file bill of costs. Mikva, Edwards and Starr, CJs.
(R)06-28-85	Receipt from Clerk, District Court dated June 26, 1985 for certified original record (1 vol.)
(R)08-14-85	Notice from Clerk, Supreme Court advising that appellee has to and including October 20, 1985 to file a petition for writ of certiorari [1]
(C)10-28-85	Notice from Clerk, SC advising that petition for writ of certiorari was filed on Oct. 18 and docketed as SC No. 85-664

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL.
PLAINTIFFS

v.

JERE GOYAN, COMMISSIONER
FOOD AND DRUG ADMINISTRATION

RELEVANT DOCKET ENTRIES

Date	NR	Filing—Proceedings
1980		
Dec. 5	1	COMPLAINT, appearance.
Dec. 5		SUMMONS (3) and copies (3) of complt. issued. Da ser 12/9/80 deft ser 1/13/81
1981		
Jan. 23	2	INTERROGATORIES by pltffs. and document production requests to deft.
Feb. 9	3	ANSWER of deft. to the complaint. Appearance of Patricia J. Kenney.
Feb. 9		CALENDARED. CAL/N.
Feb. 25	4	MOTION by deft. for an enlargement of time.
Feb. 27	5	ORDER filed 2-26-81 granting motion of deft. for enlargement of time and allowing deft. until 3-8-81 to respond to pltffs. interrogatories and document production request. (N) JOHNSON, J.
Mar. 9	6	ANSWER of defts. to pltffs interrogatories; Exhibits.
Mar. 19	7	OBJECTIONS of defts. to pltffs. interrogatories. "Leave to file granted". (fiat) JOHNSON, J.

Mar. 27	8	ORDER filed 3-26-81 referring case, *sua sponte* to the Magistrate for discovery and pretrial. (N) JOHNSON, J.
Dec. 10	9	ORDER directing that discovery be completed by 2-5-82 and any dispositive motions be filed on or before 2-26-82; pretrail will be conducted not later than 3-31-82 and the trial will commence on April 19, 1982 at 10:00 A.M. (N) JOHNSON, J.
Feb. 19	10	ORDER setting trial on 4/19/82 and directing counsel to comply with certain requirements. (N) JOHNSON, J.
Feb. 25	11	REQUEST of deft. to substitute attached page which has been corrected to read Arthur Hull Hayes, Jr., Commissioner of Food and Drug Administration; attachment.
Feb. 25	12	STIPULATION and order that pltfs will file motion for summary judgment by 3/10/82. Defts. will file cross-motion for summary judgment and opposition to pltfs. motion by 4/9/82. Pltf. will file opposition to defts. cross-motion and a reply to defts. opposition by 4/19/82. Deft. will file reply to pltfs. opposition by 4/29/82. So Ordered. (N) JOHNSON, J.
Mar. 10	13	MOTION of pltffs. for summary judgment; statement of material facts; P&A's; Exhibits.
Apr. 9	14	MOTION of defts. for an enlargement of time.
Apr. 13	15	ORDER directing that deft. will file his dispositive motion and opposition to pltfs. motion for summary judgment by

4/15/82; that pltfs. will file their opposition to defts. motion and reply to defts. opposition by 4/26/82; and that deft. will file reply to pltfs. opposition, if necessary, by 5/6/82. (N) JOHNSON, J.

1982

Apr 15	16	MOTION of defts. to exceed the thirty-five page limit; Exhibit (Opposition).
Apr 15	17	MOTION of defts. to dismiss, or in the alternative, for summary judgment.
Apr 15	18	RESPONSE of defts. to pltffs. statement of material facts as to which there is no genuine issue.
Apr 15	19	STATEMENT of material facts by defts. as to which there is no genuine dispute.
Apr 21	20	ORDER granting motion of deft. to exceed the 35 page limit. (N) JOHNSON, J.
Apr 26	21	OPPOSITION of defts. to pltffs motion for summary judgment and memorandum of points and authorities in support of motion to dismiss, or in the alternative, for summary judgment; Appendix; statement of Leonard Stoloff; statement of Taylor M. Quinn; statement of Linda M. Quinones; Exhibits.
Apr 28	22	STIPULATION extending briefing schedule as pltffs. will file opposition to deft's motion and reply to deft's opposition on or before 5/7/82; deft will file a reply to pltff's opposition if necessary on or before 5/17/82, SO ORDERED. (FIAT)(N) JOHNSON, J.

May 14	23	MOTION of the State of South Carolina for leave to file an Amicus Curiae brief; Exhibit 1; Exhibit (amicus curiae brief).
May 17	24	STIPULATION filed 5/13/82 modifying the briefing schedule of both parties, (1) Plaintiffs will file their opposition to defts motion and reply to defts opposition on or before 5/17/82; (2) deft. will file a reply to pltffs opposition, if necessary, on or before 5/27/82. (fiat) JOHNSON, J.
May 17	25	OPPOSITION of pltffs. to defts. motion for summary judgment and reply to defts opposition to pltffs motion for summary judgment.
May 17	26	RESPONSE of pltffs. to defts. statement of material facts as to which there is no genuine dispute.
May 18	27	RESPONSE of defts. to motion for leave to file amicus curiae brief by the State of South Carolina.
May 27	28	RESPONSE of pltff. to motion and brief amicus curiae of the State of South Carolina.
Jun 8	29	MOTION of deft. for enlargement of time.
Jun 11	30	REPLY of defts. to pltffs. opposition to defts motion to dismiss or in the alternative, for summary judgment.
Jun 11	31	STIPULATION filed 6/10/82 allowing defts. until 6/8/82 in which to file a reply. approved. (N) JOHNSON, J.
Jun 23	32	NOTICE by defts. to substitute the attached pages 3,4,5,6,8,9, and 12 for those filed on June 11, 1982; attachments.

Aug 18	33	APPEARANCE of Jeffrey Gibbs as counsel for defts.
Dec 15	34	REQUEST by pltffs. for oral hearing.
1983		
Aug 30	35	NOTICE by deft. of filing of supplemental statement to update the Court on the status of requested exemptions from the FDA's action level for aflatoxin level in corn; additional statement of Taylor M. Quinn.
Sep 9	36	ORDER filed 9-6-83 granting motion of the State of South Carolina for leave to file an amicus curiae. (N) JOHNSON, J.
Sep 15		MOTION of pltf. and cross motion of deft. for summary judgment heard, argued and taken under advisement. (Rep. Gloria Wiliams) JOHNSON, J. (ml)
Dec 16	37	MOTION by pltfs. for an expeditious decision on cross-motions for summary judgment; attachment. (fs)
Dec 28	38	MOTION by deft. for enlargement of time to respond to pltffs' motion filed 12-16-83. (ml)
1984		
Jan 3	39	ORDER filed 12-30-83 that deft. shall have to and including 1-5-84 to respond to pltffs' motion filed on 12-16-83. (N) JOHNSON, J. (ml)
Jan 12	40	RESPONSE by deft. to pltfs' motion for an expeditious decision on cross-motions for summary judgment. "Leave to file granted." (fiat) JOHNSON, J. (signed 1-11-84) (ml)

Feb 16	41	ORDER filed 2/14/84 denying motion of pltfs. for summary judgment; denying motion of deft. to dismiss; granting motion of deft. for summary judgment; and dismissing case with prejudice. (N) JOHNSON, J. (ml)
Feb 23	42	MEMORANDUM OPINION filed 2-17-84. (N) JOHNSON, J. (ml)
Apr 11	43	NOTICE OF APPEAL by pltfs. from order entered 2/16/84 and memorandum opinion entered 2/23/84; $5.00 filing fee and $65.00 docketing fee paid and credited to U.S. Copies mailed to Patricia J. Kenney, Thomas Scarlett and David F. Weeda. (ef)
Apr 11		COPY of docket entries, notice of appeal transmitted as preliminary record to USCA. (USCA 84-5223) (ef)

[21 CFR PART 122]

POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD

Notice of Proposed Rule Making

Elsewhere in this issue of the Federal Register the Commissioner of Food and Drugs is issuing proposed regulations concerning permitted levels of mercury in fish and shellfish (mollusks and crustaceans), lead in evaporated milk and evaporated skim milk, and aflatoxin in shelled peanuts and peanut products used as human foods. The Commissioner has concluded that Part 122, promulgated in an order published in the FEDERAL REGISTER of July 6, 1973 (38 FR 18096), should be expanded to deal with all poisonous or deleterious substances in food, including food-contact surfaces, pet food, and animal feed, to implement sections 402(a) and 406 of the Federal Food, Drug and Cosmetic Act.

Section 402(a) (1) of the act provides that a food shall be deemed to be adulterated:

If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

Section 402(a) (2) of the act provides that a food shall be deemed to be adulterated:

(A) If it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is or it bears or contains any food additive which is unsafe within

the meaning of section 409: *Provided*, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is insafe within the meaning of section 512.

Section 406 of the act permits the establishment of tolerances for added poisonous or deleterious substances in food; section 408 of the act permits the establishment of tolerances for chemicals in or on raw agricultural commodities; and section 409 of the act permits the establishment of tolerances for food additives.

The basic provision of the act dealing with poisonous or deleterious substances in food is section 402(a) (1) of the act, which applies to all poisonous or deleterious substances, whether they are naturally occurring or added. It is deliberately cumulative with the provisions relating to establishment of tolerences for food substances referenced in section 402 (a) (2) of the act and was retained from the Food and Drugs Act of 1906 because its language had been construed by the Supreme Court in United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1974). See Hearings on S. 2800 Before the Senate Committee on Commerce, 73d Cong., 2d Sess. 530 (1934). Its broad scope is shown by the fact that the related provisions in sections 406, 408(a), 409(a), and 512(k) of the act exempt a substance from section 402(a)(1) only if a regulation has been promulgated under the authority of those other sections.

Section 402(a) of the act distinguishes between naturally occurring and "added" substances and sets different standards for each. Naturally occurring substances are prohibited only if they render the food "ordinarily" injurious to health. Added substances are prohibited if they "may" be injurious to health; if such substances are necessary or unavoidable, special procedures are established by which they can be regulated.

"Added" is a statutory term of art encompassing all ingredients which are not inherent and intrinsic parts of a food. The term "added" was introduced into Federal food law in the drafting of the 1906 act when the U.S. Department of Agriculture (USDA) opposed a provision defining a food product as adulterated if it was injurious to health. The Department noted that such a provision would outlaw coffee, tea, and other foods containing deleterious ingredients as natural constituents. See the testimony of the Commissioner in Hearings on H.R. 6906, H.R. 8805, H.R. 8941, and S. 5 Before A Subcommittee of the House Committee on Interstate and Foreign Commerce, 74th Cong., 1st Sess. 58 (1935). To exempt such foods containing naturally occurring deleterious ingredients, the Senate committee considering the bill in 1906 adopted the word "added." See 40 Cong. Rec. 897 (1906). Although the word chosen implies that the statute is concerned with the act of addition, the legislative history makes clear that the term seeks rather to establish a standard based upon the necessary and inherent normal condition of the food.

Actions of the USDA after enactment of the 1906 act demonstrate that all contamination was regarded as "added." In 1914, the USDA announced that it had been investigating the presence of lead and arsenic in food, noting that such contaminants were "usually introduced into such products through the use of impure raw materials or from the apparatus or utensils employed in the processes of manufacture." The announcement further stated that "this

bureau holds that food containing arsenic or lead, added in any manner, is adulterated, in that it contains an added poisonous or deleterious ingredient which may render the product injurious to health." U.S. Department of Agriculture, Bureau of Chemistry, Service and Regulatory Announcements 312-313 dated June 23, 1914.

Throughout the hearings leading to the 1938 act, it remained clear that substance was "added" within the meaning of the statute whenever it was not inherent in nature, and not just when it was purposefully added. Thus, in explaining a proposed provision equivalent to the present section 402(a)(1) of the act, which removed the 1906 act's limitation to added ingredients, the Commissioner testified that the effect of eliminating the reference to added ingredients was to include deleterious ingredients "normal to the food product." Hearings on S. 2800, supra, at 528. The Commissioner's examples of added substances clearly included environmental and industrial contaminants. One example given of food containing an added poisonous substance was sugar contaminated by smoke from a nearby smokestack. Lead pipes, lead manufacturing equipment, and lead containers were also identified as sources of added poisonous substances. Hearings on H.R. 6906, supra, at 59-60; Hearings on S. 1944 Before a Subcommittee of the Senate Commerce Committee, 73d Cong., 2d Sess. 25, 27 (1933). The Commissioner testified at one point that some added poisonous or deleterious substances were "more or less universal," and at another time that "[t]here are very few things * * * in which you will not find contaminating products in some small degree." Hearings on S. 1944, supra, at 18; Hearings on H.R. 6906, supra, at 59. This emphasis on the ubiquity of added poisonous or deleterious substances clearly demonstrates that the term was understood to include all food contaminants.

The legislative history also identifies examples of foods naturally containing poisonous or deleterious substances and thus not subject to the "added" provisions of section 402(a)(1) of the act. These examples are Burma beans, which contain a glucoside that yields prussic or hydrocyanic acid; rhubarb, which contains oxalic acid; and coffee and tea. See Hearings on S. 1944, *supra*, at 17; Hearings on S. 2800, *supra*, at 29; Hearings on H.R. 6906, *supra*, at 58. Except for substances whose deleterious nature is inherent to the natural state of the food, and thus similar in origin to these examples, all poisonous and deleterious components are "added" within the meaning of the act. Moreover, when a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening act, it is "added" to the extent of such increase.

Judicial decisions have recognized that the scope of the "added" provisions of the law extends to all poisonous or deleterious substances not inherently a component of the food. In the United States v. 1,600,800 Pounds of White Corn, Civil No.T-4173 (D.Kan., Dec. 18, 1970), the court held that aflatoxin in corn was an added poisonous or deleterious substance within the meaning of the act since aflatoxin is not a natural constituent of corn. In *United States v. 1200 Cans, Pasteurized Whole Eggs,* 339 F. Supp. 131, 136 (N.D. Ga. 1972), the court recognized that salmonella in eggs is an added poisonous or deleterious substance.

Section 406 was included in the 1938 act to permit the establishment of tolerences for added poisonous or deleterious substances which are required in the production of food or otherwise cannot be avoided by good manufacturing practice. A limitation may be placed upon such substances to the extent necessary for the protection of the public health. Although formal tolerances under section 406 have been used by the Food and Drug Administration, except for the tolerance for PCB's published

in the FEDERAL REGISTER of July 6, 1973 (38 FR 18096), informal action levels have frequently been utilized to implement this provision of the law and a number of those action levels exist today. In the past, such action levels have been issued through press releases and other public announcements but have not been published in the FEDERAL REGISTER or codified as regulations.

Section 408 was added to the act in 1954 to permit the establishment of tolerences for pesticide chemicals in or on raw agricultural commodities. This provision of the law was administered by the Food and Drug Administration (FDA) until the establishment of the Environmental Protection Agency (EPA) in 1970.

In 1958, Congress enacted the Food Additives Amendment, which affected the legal status of some of the contaminants previously regulated only as added poisonous or deleterious substances. The legislation was basically in two parts: first, a broad definition of "food additive" and a general prohibition of food additives not demonstrated to be safe; and second, a procedure by which the use of safe food additives could be approved. This two-part approach was the congressional answer to what was identified as a "dual problem." See H.R. Rep.2284, 85th Cong. 2d Sess.1 (1958). The first part of the problem was that under section 402(a)(1) and (2)(A) of the act, the burden is on the Government to show that a food substance is poisonous or deleterious. As the House Commerce Committee noted,"to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food." The amendment therefore shifted the burden of proof in enforcement actions brought against food containing poisonous or deleterious substances to the food manufacturer.

The definition of "food additive" established in section 201(s) of the act is not limited to intentional additives. The

breadth of the language in section 201(s) of the act includes any food substance and excludes only those substances which cannot reasonably be expected to become a component of food. The statutory definition thus includes what are referred to as "incidental additives" as well as "intentional additives". See H.R. Rep. No. 2284, supra, at 3. Any added poisonous or deleterious substance in food, unless accidental and unforeseeable or specifically exempted by section 201(s) of the act, is a food additive. A food naturally containing a poisonous or deleterious substance becomes a food additive if it is not generally recognized as safe and is added to other food or undergoes processing. Food-packaging material may also contain food additives.The broad scope of section 201(s) of the act has been judicially recognized in United States v. Ewig Bros. & Co., Nos. 73-1008, 73-1454 (7th Cir., Aug. 28, 1974), and United States v. City Smoked Fish Co., Civil No. 33989 (E.D. Mich. 1970,1972) in which DDT in smoked fish was held to be a food additive. The court in United States v. Articles of Food, 370 F.Supp. 371 (E.D. Mich. 1974), held that substances migrating from pottery plates are food additives.

The Food Additives Amendment of 1958 was also intended to rectify the second part of the dual problem which was that "present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies." H.R. Rep. 2284, supra, at 1-2. Section 409 of the act was enacted to permit issuing a regulation prescribing the conditions under which an additive may be safely used. Before any such regulation can be issued, the statute requires that the safety of the food additive be demonstrated. The statute also requires that the food additive accomplish a physical or other technical effect and requires the regulation to restrict use of the food additive to the lowest level necessary for that purpose.

When the Food Additives Amendment of 1958 was enacted, the provisions of section 406 of the act were not repealed. Although all added poisonous or deleterious ingredients are food additives, except when they appear in food accidentally and unforeseeably or are exempted under section 201(s) of the act because they are otherwise regulated under the act, the tolerance-setting provisions of section 406 of the act were left intact to deal with those unavoidably added poisonous or deleterious ingredients that could not meet the high standards for issuance of a regulation under the authority of section 409 of the act. A number of added poisonous or deleterious substances, which are also food additives within the meaning of section 201(s) of the act, are unavoidable but cannot meet the requirements for a section 409 regulation because their safety cannot be demonstrated and because they serve no functional purpose. A prominent example is lead, which was one of the contaminants most frequently mentioned in the legistative history of the 1938 act and one of the prime contaminants with which section 406 was enacted to deal. Lead cannot be the subject of a food additive regulation under section 409 of the act even at trivial levels because it serves no functional purpose. Section 406 of the act, therefore remains in force to control the use of such substances, since there would otherwise be no statutory means available to recognize their unavoidability and to exercise reasonable control over their presence.

Thus, there is nothing in the language of section 402(a)(2)(A) of the act to prevent issuance of a regulation under section 406 of the act for an added poisonous or deleterious substance that is also a food additive and for which no food additive regulation has been or can be promulgated. Section 402(a)(2)(A) of the act deems a food adulterated "if it bears or contains any added poisonous or deleterious substance (other than one which is * * * (ii) a food additive * * *) which is unsafe within the meaning

of section 406". If the parenthetical exception had been meant to prohibit issuance of section 406 tolerances for food additives, the exception would have been placed in section 406 of the act. Instead, the language of section 406 of the act allowing the Secretary of Health, Education, and Welfare to promulgate tolerances remains in full effect. Section 406 of the act must, of course, be read as having equal force and effect as the other parts of the statute.

The parenthetical exception was placed in section 402 of the act, the section dealing with the legal definitions of adulteration, rather than in section 406 of the act, the authority to promulgate tolerances, because the intention was to exempt a food additive from the provisions of section 406 of the act once a section 409 regulation has been promulgated. The parenthetical exception is thus similiar to the language in sections 406, 408(a), 409(a), and 512(k) of the act granting an exemption from section 402(a)(1) of the act if a regulation under one of those sections is in effect.

The correctness of that interpretation is confirmed by the language of the proviso in section 402(a)(2)(C) of the act. That proviso creates an exemption from the food additive provisions of the act for a pesticide in a processed food under certain circumstances. In doing so, the proviso refers to both sections 406 and 409 of the act. A reference to section 406 of the act would obviously not have been necessary to exempt a substance from the provisions of the act applicable to food additive if the language of section 402(a)(2)(A) of the act made the provisions of section 406 of the act inapplicable to food additives. Instead, because the proviso deals with a situation in which no section 409 regulation will be issued, the reference to section 406 of the act is necessary to afford complete exemption.

Similarly, when a tolerance for an unavoidable pesticide cannot be issued under the criteria of section 408 of the act, section 406 is available to control its use. Under the

Executive Order establishing it, the EPA promulgates tolerances under sections 406, 408 and 409 of the act for pesticides in or on food and the FDA is then responsible for enforcing those provisions.

The Commissioner proposes to establish procedures for controlling all poisonous or deleterious substances. Basic reliance on the provisions of section 409 for regulating use of such substances remains unchanged, and regulations issued under that authority are set forth in 21 CFR Part 121. However, when a food contaminant is unavoidable but cannot be approved under the criteria of section 409 of the act, a formal procedure is being proposed to control its use under the authority of sections 306, 402(a), and 406 of the act.

When a tolerance is established under the provisions of section 406, the act requires it to be set at the level necessary for the protection of the public health taking into account the extent to which the substance cannot be avoided and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

At times it will not be appropriate to establish a formal tolerance. The Commissioner is not required to establish a tolerance for every added poisonous or deleterious substance, as is indicated by the language of section 406 of the act recognizing that an adulteration charge can be made under section 402(a)(1) of the act when no tolerance is in effect. Section 306 of the act has long been interpreted to permit the Food and Drug Administration to establish action levels in implementing the adulteration provisions of the act. See United States v. Goodman, 486 F.2d 847 (7th Cir. 1973); United States v. Thriftimart, Inc., 429 F.2d 1006, 1011 (9th Cir. 1970); United States v. 1500 Cases More or Less, Tomato Paste, 236 F.2d 208, 211-12 (7th Cir. 1956); United States v. 449 Cases Containing Tomato Paste, 212 F.2d 567, 572-73 (2d Cir. 1954); United

States v. 133 Cases of Tomato Paste, 22 F.Supp.515, 516 (E.D. Pa. 1938); cf. United States v. Ewig Bros. & Co., supra.

When the factors required to be considered prior to promulgation of a section 406 tolerance are rapidly changing, it would be inappropriate to set such a formal tolerance. The procedures required by section 406 of the act, including a public hearing and requirement of substantial evidence to support the tolerance, contemplate ample evidence to consider, and a relatively stable situation where the evidence will be of more than transient significance and where the tolerance eventually promulgated will be appropriate for a relatively long period of time. For example, if industrial practices are improving so quickly that the extent to which the substance is unavoidable changes significantly from year to year, there is little justification for use of section 406 procedures. Similarly, if toxicological data are scanty or conflicting, but additional data are being developed, it would serve no good purpose to labor over an assessment of the existing data in a public hearing while ignoring the prospects of additional studies. The Commissioner therefore concludes that the structure and criteria of section 406 of the act indicate it is to be used primarily in relatively static circumstances.

When it is not appropriate to promulgate a tolerance under section 406, it may nevertheless still be appropriate to take some formal regulatory action to control use of a substance. In such circumstances, the Commissioner will consider promulgating an action level under authority of sections 306, 402(a), and 406 of the act.

Such action levels are similar to a formal tolerance in basis and effect. In setting an action level, the Commissioner considers evidence indicating when the presence of an added poisonous or deleterious substance may render food injurious to health, which is the standard in section 402(a)(1) of the act. In addition, the Commissioner takes into account the question of its unavoidability, a policy

embodied in section 406 of the act. Thus, an action level is based on the same criteria as a tolerance, except that an action level is temporary until the appearance of more stable circumstances makes a formal tolerance appropriate.

Particular problems are raised with respect to the use of pesticides, which frequently result in environmental contamination. Tolerances under section 406 of the act may be issued by EPA which allow for residues of pesticides in food, even though the pesticide itself is not registered by EPA for use with that particular crop.

An action level may also be established for a pesticide for which the EPA has not issued a tolerance under section 406 of the act. Because of their joint pesticide responsibilities under the act, the EPA and the FDA agree that both agencies have definite roles in respect to action levels for pesticides. Since action levels are an exercise of enforcement discretion, and since FDA is responsible for enforcement under the Executive Order establishing EPA, FDA is responsible for determining when an action level for a pesticide should be established and issuing such actions levels as regulations. Since action levels are similar to a formal tolerance in basis and effect, and since EPA has the expertise to establish pesticide tolerances, EPA is responsible for determining upon request from FDA, the appropriate level at which a pesticide action level is to be set.

Such tolerances or action levels properly recognize the problem of environmental contamination caused by drift of a pesticide from one area to another, or the persistence of the chemical in the environment over a period of time. In no instance, however, does any such action level or tolerance itself authorize use of any pesticide on a food crop for which it has not been registered by EPA. Except in the limited instances discussed below, no action level or other administrative action will be taken to permit the sale of food contaminated with a pesticide that has been used in any manner other than in strict accordance with the label directions approved by EPA.

The establishment of a tolerance or an action level does not authorize use of the particular poisonous or deleterious substance involved, or mean that any product containing up to that level of contamination is necessarily a lawful product. The failure to comply with the requirements of section 402(a)(4) of the act, which prohibits the preparation, packaging, or storage of food under insanitary conditions, is a separate violation of the act, even if the food itself does not violate any tolerance or action level for added poisonous or deleterious substances. Similarly, blending a contaminated food with a noncontaminated food, to produce a final product that falls within a tolerance or action level, is unlawful under the act and is prohibited by the proposed regulations.

The proposed principles and procedures set forth in Part 122 apply equally to imported food. Any food additive or pesticide intentionally used in or on imported food must be the subject of a regulation issued under section 408 or 409 of the act. Unavoidable added poisonous or deleterious substances may be the subject of a tolerance or action level issued under Part 122.

Because of enforcement practicalities, tolerances and action levels for imported food must be the same as for domestically produced food, although levels of unavoidable contamination may differ from country to country. For example, some pesticides are approved for use abroad because of conditions which justify their use, but are not registered for use in this country because those conditions do not exist here. In such a case, a regulation issued by EPA under section 408 or 409 of the act would apply to any food on which the pesticide was intentionally used. A tolerance may be issued by EPA or an action level by FDA, however, to be applied to food unavoidably contaminated by the pesticide. That tolerance or action level will be set at a uniform level for all food, including

domestic food. The establishment of the tolerance or action level would not authorize any use of the pesticide in this country, however.

The Commissioner intends to issue, by publication in the FEDERAL REGISTER, all existing action levels for unavoidable poisonous or deleterious substances as regulations in Part 122. In the interim, these publicly known action levels will continue in effect. Although the Commissioner intends to issue as regulations all new action levels as well, circumstances may require use of informal action levels pending issuance of final regulations. Such informal action levels will continue to be announced to the public.

Finally, the Commissioner recognizes that there may be some circumstances where it will be in the public interest to permit the marketing of food that is contaminated with a poisonous or deleterious substance, even though the contamination may have occurred through unlawful or other avoidable misuse of the substance and thus the food would not be eligible for a tolerance or action level. This would occur where a large amount of food is contaminated, resulting in a substantial adverse impact on the national food supply, and all available toxicological data indicate that no significant health hazard is involved. Accordingly, the proposed regulations provide a public procedure whereby, under such circumstances, the Commissioner may permit the marketing of such food, as an exemption from the usual rules that would be applicable. Any such exemptions would be limited to a single occurrence and would be decided on an ad hoc basis after public consideration of the issues involved.

The proposal also prescribes a method of issuing regulations to deal with foods containing naturally occurring poisonous or deleterious substances. Where appropriate, the Commissioner may identify foods which, because of their inherent components, are deemed to be adulterated

within the meaning of section 402(a)(1) of the act. These regulations would, of course, not constitute a complete list of such foods.

In the FEDERAL REGISTER of September 23, 1974 (39 FR 34172), the Commissioner consolidated existing regulations on substances prohibited from use in food in a new § 121.106 (21 CFR 121.106). Prohibited food additives will continue to be listed in Part 121, and Part 122 will be used only to identify foods prohibited even when not used as food additives. Since neither of these lists is exhaustive, the appearance of a food or of a poisonous or deleterious substance on one of the lists while not on the other does not constitute a determination that it should not appear on the other.

In addition, the proposal creates a method whereby interested persons can petition the Commissioner to establish a tolerance, action level, or other regulation under this part. Petitions adequately supported would be published in the FEDERAL REGISTER for comment.

No action is proposed for polychlorinated biphenyls (PCB's) (21 CFR 122.10) except recodification as § 122.100. The renumbered section is set forth in its entirety as part of the revision for the convenience of the reader. Additionally, paragraph (a)(9) of that section was stayed by an order published in the FEDERAL REGISTER of August 24, 1973 (38 FR 22792).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 406, 408, 409, 701(a), 52 Stat. 1045-1046 as amended, 1049, 1055, 68 Stat. 511 as amended; 72 Stat. 1785-1788 as amended; 21 U.S.C. 336, 342(a), 346, 346(a), 348, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 122 be revised to read as follows:

PART 122 – POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD AND FOOD-PACKAGING MATERIAL

Subpart A – Definitions and Procedures

Sec.
122.3 Definitions:
122.4 Establishment of regulations:
122.5 Petitions.
122.6 Added poisonous or deleterious substances.
122.7 Unavoidablity.
122.8 Exemptions.

Subpart B – Tolerances for Added Poisonous or Deleterious Substances

122.100 Polychlorinated biphenyls (PCB's).

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045-1046 as amended, 1049, 1055-1056 as amended, 68 Stat. 511, as amended; 72 Stat. 1785-1788 as amended (21 U.S.C. 336, 342(a), 346, 346(a), 348, 371).

Subpart A – Definitions and Procedures

§ 122.3 Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other handling or contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is

increased to abnormal levels through mishandling or other intervening act, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

§ 122.4 Establishment of regulations.

(a) When appropriate under the criteria of § 122.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may be established at the level of zero.

(b) When appropriate under the criteria of § 122.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart C of this part to define the level of contamination at which a food will be deemed to be adulterated under section 402(a)(1) of the act. An action level may prohibit any detectable amount of the substance in food.

(c) A regulation may be estabished in Subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 122.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 2.65 of this

chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 122.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a regulation issued under section 406, 408, or 409 by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established at a level specified by EPA pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under authority appropriate for action levels as well as under authority appropriate for tolerances. In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection and request for hearing, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

§ 122.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The manufacturer

of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

(c) The mixing of a food containing a poisonous or deleterious substance in an amount above the tolerance or action level with another lot of food is not permitted and renders the final food unlawful regardless of the amount of poisonous or deleterious substance in the final food.

§ 122.8 Exemptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a proposal in the FEDERAL REGISTER, with time for public comment whenever feasible. The time permitted for comment shall depend upon the degree of urgency required by the specific matter involved. In the event that no time for comment is feasible, the exemption may be issued as a final determination rather than as a proposal.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies (e.g., the specific growing area or other identifying information). The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant

to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

Subpart B—Tolerances for Added Poisonous or Deleterious Substances

§ 122.100 Polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this

paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufactured dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this

section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 4–65, 5600 Fishers Lane, Rockville, MD 20852.

Interested persons may, on or before March 6, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852 written comments (preferably in quintuplicate) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 29, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

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[21 CFR Part 122]

AFLATOXINS IN SHELLED PEANUTS AND PEANUT PRODUCTS USED AS HUMAN FOODS

Proposed Tolerance

Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner of Food and Drugs is issuing proposed procedural regulations concerning the control of poisonous or deleterious substances in food. In accordance with those proposed procedures and principles, the Commissioner is issuing a proposal for a tolerance for aflatoxins in shelled peanuts and peanut products used as human foods.

Under certain environmental conditions, molds grow on and contaminate some of the foods we eat. Historically, mold contamination of food has been considered as an aesthetic problem; however, there have been numerous instances where consumption of moldy food or feed resulted in illness or death to humans or animals (references 1,2,3, and 4). In some of these cases, it was determined that the

cause was certain toxic chemical compounds produced by the molds. These compounds are known as mycotoxins (*mykes,* from the Greek, meaning mold). There are many known mycotoxins, but only a few have been found as food contaminants (reference 4).

The recent concern over mycotoxins was brought about by the discovery in the early 1960's of a specific group of mycotoxins known as aflatoxins (reference 1). The aflatoxins are chemically related substances produced by the common molds *Aspergillus flavus* (hence the name aflatoxins, from A. *flavus* toxins) and by *Aspergillus parasiticus.* The term "aflatoxins" also refers to a number of other related chemicals, which either are of synthetic origin or are produced biologically by animals fed aflatoxins. In this document, the terms "aflatoxin" and "aflatoxins" will include only the four common mold-produced aflatoxins known as B_1, B_2, G_1, and G_2.

Aflatoxims may contaminate foods whenever the producing molds grow on foods under favorable conditions of temperature and humidity. The presence of an aflatoxin-producing mold on a food does not necessarily imply the presence of the aflatoxins. Conversely, the absence of obvious growth of an aflatoxin-producing mold does not mean the absence of the toxins, since aflatoxins may be produced when there is little evident mold growth. Furthermore, aflatoxins may remain in a food product after processing has obscured or otherwise eliminated visible mold (references 3 and 4). Under laboratory conditions, a large number of foods can support the growth of aflatoxin-producing molds; under natural conditions in the field, natural competition determines which molds will grow and which mycotoxins will be produced. Corn, barley, copra, cassava, tree nuts, cottonseed, peanuts, rice, wheat, and grain sorghum are subject to natural aflatoxin contamination (reference 4). In

the United States, aflatoxins have been detected only in corn, figs, grain sorghum, cottonseed, certain tree nuts, and peanuts (reference 5).

Aflatoxins are present in peanuts and peanut products because of these contaminating molds. They are, therefore, added substances within the meaning of the Federal Food, Drug, and Cosmetic Act. The meaning of that term is discussed in detail in the preamble to the proposed procedures and principles for the control of poisonous and deleterious substances published elsewhere in this issue of the FEDERAL REGISTER.

The Commissioner has a two-fold concern with aflatoxins. First, animals fed aflatoxins are subject to acute tonic effects. Second, and of primary concern, data which indicate that these substances, particularly aflatoxin B_1, found in some species of test animals are among the most potent liver carcinogens known (references 1, 2, and 3).

The acute toxic effects of the aflatoxins are of little concern in the United States, since our agricultural and marketing processes assure that heavily molded food, which might contain levels of aflatoxins associated with such effects, does not enter the human food chain. Of great concern is the effect of long-term, low-level ingestion (i.e., chronic toxicity effects), particularly the carcinogenic effects (references 6, 7, and 8).

While there is no direct evidence that aflatoxins are a cause of liver cancer in man in the United States, their extreme potency as hepatocarcinogens in some animal species does furnish a foundation for the Commissioner's concern. The carcinogenicity of aflatoxins has been demonstrated in rats, monkeys, rainbow trout, ducks, ferrets, and mice (references 6, 7, and 8).

Aflatoxin carcinogenesis has been studied most extensively in rats. There have been several experimental studies with rats, and liver carcinomas have been produced in a number of different strains (reference 7).

In one study, highly purified aflatoxin B_1 was fed continuously to 25 rats for a period of 68-80 weeks. The level of aflatoxin in the diet was 15 parts per billion (ppb). All 25 rats developed liver carcinoma (reference 9). In a later study with the same strain of rat, liver carcinoma was produced in 2 out of 22 rats exposed for 105 weeks to a diet containing only 1 ppb aflatoxin B_1 (reference 9). These two studies demonstrate the extreme potency of aflatoxin B_1 as a liver carcinogen; however, other experimental studies furnish evidence that there are marked differences in the incidence of liver carcinomas in rats produced by various levels of aflatoxins depending on such variables as composition of the diet, age of the test animals, strain of rats used, and length and type of exposure (reference 7). The extreme difficulty in drawing conclusions from all of these studies is indicated by one study in which one strain of rat exposed to aflatoxins at a level of 80 ppb for 90 weeks suffered some liver damage, but no cancer (reference 10).

Liver cancer has been produced by ingestion of aflatoxins in three Macaque monkeys. One was exposed to an average of 0.02 milligram per kilogram (mg/kg) body weight daily for 5½ years. The other two were exposed to an average of 0.06 mg/kg body weight for 6 years (reference 8).

Epidemiological studies bearing on the possible effects of aflatoxin in man have been performed on specific population groups in Southeast Asia and Africa, where there is a known high incidence of primary liver cancer (references 8 and 11). In these areas, the climate and agronomic practices were expected to be conducive to production of aflatoxins in food. In one of the areas studied, 95 percent of the corn and 80 percent of the peanut samples had average aflatoxin levels around 100 ppb. In another area, 20 percent of the food staples contained aflatoxin levels averaging 300 ppb. In a third area,

there was a high incidence (7 percent) of low levels (3-4 ppb) of aflatoxins in family meals. The result of these studies is an indication of a general correlation between the incidence of primary liver cancer in humans and the exposure to aflatoxins (reference 11).

No epidemiological studies of these types have been carried out in the United States. However, primary liver cancer is a minor form of cancer in the United States, accounting for about 0.7 percent of all cancer cases (reference 12). In addition, cancer rates in those areas of the United States where climatic conditions are most conducive to aflatoxin contamination (i.e., the southeastern states) do not differ significantly from other areas (reference 13). Domestic profiles for primary liver cancer differ in sex and age from those observed in "high incidence" countries (reference 13). One study in a major city in the United States shows some degree of correlation between primary liver cancer and alcoholism (reference 14).

Thus, while it is not certain that aflatoxins are a cause of primary liver cancer in the United States, the Commissioner concludes that the observations of severe carcinogenic effects in experimental animals and positive correlations between dietary aflatoxins and primary human liver cancer seen in other parts of the world are sufficient justification to regard aflatoxins as poisonous or deleterious substances and to take actions to hold human exposure to aflatoxins in the United States to the lowest level possible. Shortly after the discovery of the presence of aflatoxins in peanuts (reference 15), the Food and Drug Administration (FDA) began a program for their control (references 5 and 16). In 1965, the FDA established an informal action level of 30 ppb total aflatoxins. In 1969, it was reduced to the current level of 20 ppb total aflatoxins.

The informal action level of 20 ppb has been applied to all affected commodities. As more is learned about the extent to which contamination of foods by aflatoxins can be avoided, FDA will systematically and formally adjust its

action level to reflect this new knowledge either as an action level or tolerance. Since different agricultural products become contaminated in different ways and since the potential for removing contamination during processing differs from one product to another, the extent to which aflatoxin contamination can be avoided is commodity dependent. Action levels or tolerances will be established, then, on a commodity-by-commodity basis. In each case, the action level or tolerance will be consistent with the concept that the total human exposure to aflatoxins must be as low as possible.

At the present, there exists a body of information upon which to judge the extent to which aflatoxin contamination can be avoided in shelled peanuts and peanut products used as human food, and a reconsideration of the action level for these commodities is in order. FDA is in the process of collecting relevant information on other affected commodities. When this information becomes adequate in scope and content, adjustments in the acceptable level will be made for each of the other affected products. Until then, the 20 ppb action level will be maintained.

It is now known that aflatoxins can contaminate peanuts during any of several stages: growth, harvest, shipment, or storage. Whether mold develops at any or all of these stages depends on such factors as kernel damage, temperature, moisture, and availability of oxygen (references 17 and 18).

Although aflatoxin contaminated peanuts can be found prior to harvest, the major point of contamination, by all available evidence, is the curing process. Once mold invasion takes place, aflatoxins may be produced unless the moisture content is rapidly reduced to a level unfavorable to mold growth (references 17, 18, and 19).

Employed properly, artificial drying is an effective way to control contamination; nevertheless, large quantities of peanuts are still dried naturally, thereby risking contamination due to unfavorable weather conditions

(reference 17). Fuel shortages are apt to increase the problem, since artificial drying may give way to natural, open air drying practices.

Damage to the peanut shell may be one of the most significant factors leading to mold growth and aflatoxin contamination. It has been demonstrated that the removal of damaged kernels can lead to a major reduction in the aflatoxin levels in peanuts (references 15 and 19). Insect infestation is one source of damage; however, many kernels are damaged as the result of mechanical harvesting techniques (reference 17). Once the natural barrier imposed by the shell is breached, mold invasion can begin.

Fungicides, crop rotational practices, and other good agronomic practices can ameliorate the problem to an extent (reference 17). It is impossible at this time totally to eliminate all of the breakdowns that can occur in the total process of growing, harvesting and storing peanuts. Adverse weather, insects, improper harvesting methods, and general ignorance of the problems and solutions will be with us for some time to come. Thus, in practice, the complete prevention of mold growth and aflatoxin production in peanuts appears unattainable at the present time.

Processors of shelled nuts can eliminate some contaminated material by using a number of standard manual, mechanical, and electronic sorting procedures. Although these procedures were originally designed to remove the damaged, discolored, and immature nuts which affect appearance and flavor, they have been useful in removing aflatoxin-containing peanuts, since contamination is often associated with such peanuts (references 15, 20 and 21). Sorting does have a major limitation in that intact, sound, mature kernels can contain aflatoxins (reference 22). Due to this and other as yet unidentified reasons, there is a limit, not easily definable, to the effectiveness of sorting techniques.

The ordinary process of roasting peanuts results in some reduction of average aflatoxin level, but complete elimination of aflatoxins cannot be accomplished by the process (reference 23).

In order to detect the presence of aflatoxins in peanuts, it is necessary to have analytical methods of adequate sensitivity and specificity. Such methods are available and their effectiveness has been demonstrated by interlaboratory collaborative studies. These are now official methods of the Association of Official Analytical Chemists (AOAC) (references 3, 24, and 25). AOAC Method I can be used to detect aflatoxins B_1, B_2, G_1, and G_2 in peanut products at levels as low as 1-2 ppb (total aflatoxins). AOAC Method III, although not as accurate as Method I at low levels (2-10 ppb), is much more rapid and is used as an industrial quality control method (references 25, 26, and 27). Tests for confirmation of indentity of measured aflatoxins B_1 and G_1 have also been studied collaboratively and are official AOAC (reference 24).

While the analytical methods are a source of variability in the assay for aflatoxins, the greatest source of variability is sampling. Contamination is usually confined to a small number of kernels and there is thus no practical sampling plan which can assure that a sample is truly representative of the entire lot under investigation. Therefore, any practical sampling plan must be based on certain distribution assumptions and can assure only a limited level of confidence that a particular sample is representative of a lot (reference 28).

FDA regulation of finished peanut products has been only a part of the total control picture. The U.S. Department of Agriculture (USDA), through its Peanut Marketing Agreements, had been involved in establishing and maintaining sampling and analysis procedures designed to remove lots of peanuts showing visible A. *flavus* mold and lots of aflatoxin-contaminated raw peanuts

prior to finished product manufacture (references 16 and 29). FDA has been involved in this program on a consulting basis and receives yearly, for analysis and evaluation, the USDA reports of analyses of raw, shelled peanuts (reference 30). This program requires that all shelled peanuts offered for sale to manufacturers or wholesalers be sampled and analyzed for aflatoxins by a laboratory certified as competent by the Peanut Administrative Committee (references 5 and 21). A negative certification means that the sample assay is not over 25 ppb total aflatoxins (reference 21).

Once a lot of peanuts is sampled and assayed, it may or may not be tested again as practices vary among manufacturers. Some manufacturers do maintain their own in-house laboratories, or contract for testing services through independent or government laboratories. Others perform no further testing at all, relying on the processing procedure to remove the aflatoxins.

Since the inception of this system of controls, sampling and analysis by FDA has turned up few violative samples of finished peanut products (reference 5). FDA surveillance, however, has been limited. In 1973, the agency conducted its first large survey of the nation's peanut products. This was done to determine the nature of the quality control procedures being utilized by manufacturers to remove contaminated peanuts and the effectiveness of these procedures (reference 31).

The survey was also used to determine the distribution of various levels of aflatoxins in the nation's peanut product supply. These survey data are used as one of the considerations in establishing a tolerance for aflatoxins in peanut butter and other peanut products. All analytical data gathered in surveys of this type and reported here include the errors associated with sampling and analysis of aflatoxins.

The FDA survey encompassed 146 peanut butter and/or peanut product manufacturers. Of prime concern was geographical and size distribution, with the greater emphasis on smaller concerns where the poorest operating procedures and quality control were presumed to exist. A checklist was provided to each FDA inspector to ensure uniform reporting and data retrieval. From the 146 establishments, 361 samples of peanut butter and other finished peanut products (generally unground) were collected.

Aflatoxins levels above the action level (total aflatoxins, 20 ppb) were found in 4 percent of the 141 peanut butter samples and 2 percent of the 220 samples of unground peanuts. These samples with levels above the action level came from 5 percent of the establishments inspected. Detectable aflatoxins (greater than approximately 1 ppb) were found in 25 percent of the peanut butter samples and 10 percent of the unground peanut samples. These samples came from 22 percent of the establishments inspected. There is a large error inherent in sampling unground nuts for aflatoxins compared to the blended product, peanut butter. This precluded drawing a statistically valid inference that the incidence of aflatoxins in unground nuts is lower than that in peanut butter.

The data were examined for possible correlations between aflatoxin findings and size of the establishment, between aflatoxin findings and manufacturing practices related to control of aflatoxin contamination, and between aflatoxin findings and the aflatoxin level in the raw peanuts used.

Aflatoxin levels above 20 ppb were found only in the small and medium size establishments; however, 50 percent of the 10 largest establishments provided samples with detectable aflatoxin, compared to 23 percent of the 136 small and medium size establishments (reference 31).

No correlation between establishment size and incidence and degree of contamination could be found for the establishments inspected.

In the instances where aflatoxin contamination was found in the consumer product, there was no obvious correlation between the levels of aflatoxin found and the various manufacturing practices used (reference 31). The same observation holds for both peanut butter and unground peanuts.

There were indications that the processing of peanuts could result in a reduction of aflatoxin level to a trace of nondetectable level. However, the level of aflatoxin in raw peanuts was not consistently related to the level in the consumer product. In 15 instances, the level in the consumer product was higher than that found in raw peanuts. This result emphasizes the difficulty in obtaining a representative sample of the granular product (raw peanuts), as aflatoxin contamination may be extremely heterogeneous within a lot (reference 31).

The presence of detectable levels of aflatoxins in consumer products could result either from faulty application of the reported inspection and sorting practices or a peculiarity in the nature and distribution of the contamination. The latter possibility has some justification since aflatoxin has been found in otherwise sound, undamaged kernels.

One important conclusion which derives from all of these findings is that current manufacturing capabilities cannnot consistently assure the complete elimination of aflatoxin-contaminated peanuts from a lot during processing. What level can be consistently reached is determined by a detailed consideration of the FDA and other survey data, including those gathered by the USDA analyses of peanut butter produced under government contract and those collected by the Canadian Health Protection Branch (reference 30).

Thus, in determining an acceptable level for aflatoxins in shelled peanuts and other peanut products, the Commissioner considered all of the available information and sought to bring into balance four factors:

1.The need to minimize human exposure to aflatoxins;

2.The capabilities of sampling procedures and analytical methods to detect, measure and confirm the aflatoxins;

3.The capability of agricultural and manufacturing technology to prevent and remove contaminated peanuts; and

4.The need for the continued availability of a low cost protein source (i.e., peanuts (reference 32)).

Survey data (FDA, USDA, and Canadian) indicate that since 1971 an average of 93 percent of sampled peanut products contained aflatoxins below the 20 ppb level (references 30 and 31). The Commissioner concludes that current agricultural and manufacturing technology is capable of meeting a level below that which it is now being asked to meet. Although the immediate result of lowering the level may be the loss of a small percentage of the peanut supply, improved producer practices should compensate for any short-run loss.

Obviously, for complete protection, aflatoxins should be eliminated from food, but this is not presently feasible. Therefore, it is necessary for the Commissioner to weigh the consequences of possible levels above zero.

Setting a level at 5 or 10 ppb was considered by the Commissioner. Eleven of the 12 major U.S. manufacturers of peanut butter could meet a 10 ppb level in 90 percent of their products (reference 33). The Canadian government survey of 1972 indicated that 95 percent of the samples of peanut butter could meet this standard. However, there is year-to-year variability in aflatoxin contamination of the peanut crop. The FDA survey of 1973 evidenced the fact that only 89 percent of the peanut butter samples and 82 percent of the establishments surveyed

met a 10 ppb level. Of the 12 largest establishments surveyed, only seven met a 5 ppb limit in 90 percent of their samples (reference 33). There are also data showing that in some years only about 60 percent of the peanut butter produced met a 5 ppb level (reference 30). One bad crop year could effectively eliminate a large percentage of peanut products from the market. Thus, a move to 5 or 10 ppb could result in significant losses to producers, manufacturers, and consumers alike.

These increased losses of food would result in much higher prices (reference 33) or in unavailability of what is generally considered a highly nutritious and useful food.

Another important consideration concerns setting a tolerance at a level at which manufacturers have the capability to monitor their products during processing and ensure that the finished product complies with the tolerance. Manufacturers of peanut products now monitoring their production set analytical limits for their products in the range 5 to 10 ppb to ensure that their finished products do not exceed the current 20 ppb action level; this factor must be built into a quality control operation because of the large error associated with sampling and analysis. Setting a tolerance level of 5 to 10 ppb for aflatoxins in peanut products would have the effect of requiring manufacturers to employ an analytical limit of less than 1 to 5 ppb for quality control purposes. Because present sampling and analytical methodologies have considerable error at the 1-5 ppb range, analytical results obtained for such quality control samples would not accurately represent the production lot from which the sample was drawn. Therefore, the capability of manufacturers to control their production at these levels is extremely questionable, and to guard against the release of products containing levels of aflatoxins in excess of 5 or 10 ppb is not possible.

It would serve no useful purpose to establish a tolerance at a level at which current sampling and analytical procedures are such that compliance with the tolerance is unachievable.

In addition, because there is no direct evidence that aflatoxins cause cancer in man or of what may be the level of no effect, the Commissioner cannot conclude that there is any tangible gain from lowering the permissible level to either 10 or 5 ppb. Such uncertain benefit to the public health must be weighed against the clear loss of food that would result.

On the basis of these considerations, the Commissioner concludes that justification does not exist for implementing a maximum permissible level at either 10 or 5 ppb.

A level of 15 ppb represents a lowering of the level from the 20 ppb level which has stood since 1969. FDA survey data indicate that 93 percent of the lots of peanut butter and 97 percent of the lots of other peanut products could meet the 15 ppb level (reference 31).

Survey data from the the Canadian Government and from USDA show that, on the average, 97 percent of the lots of peanut butter sampled since 1971 could meet the proposed level (reference 30).

The Commisioner concludes that existing agricultural and industrial technology can combine to yield finished peanut products at or below a 15 ppb level without causing significantly increased losses of food. This level will also allow manufacturers to maintain capability for monitoring their products during processing with nearly as much reliability as could be attained with a 20 ppb level. At the same time, the lowering of the allowable level to 15 ppb will result in decreased human exposure to aflatoxins.

In setting a tolerance or action level, the Commissioner considers the other ways in which the consumer may be affected by the same substance or by other substances. Since there is no known acceptable level of intake of aflatoxins

and the proposed tolerance is set at the lowest practicable level, the existence of other poisonous or deleterious substances do not affect the level proposed for aflatoxin in shelled peanuts and peanut production.

The regulation also prescribes sampling and analytical methods by which compliance with the proposed limitation will be determined. Because of possible variation in the results obtained by the analytical method prescribed, the regulation provides that the average of duplicate analyses shall be used.

Taking into account (1) the fact that aflatoxins cannot be avoided by current agronomic and manufacturing processes; (2) the extent to which aflatoxins are unavoidable; (3) the data on the effects of aflatoxins; and (4) the other ways in which the consumer may be affected by aflatoxins and other substances, the Commissioner proposes to establish a tolerance for aflatoxins in shelled peanuts and peanut products used as human food, above which such products will be deemed unsafe within the meaning of section 406 of the act. Accordingly a tolerance of 15 ppb is proposed.

Pending a final regulation, FDA will continue to apply for enforcement purposes an action level of 20 ppb for aflatoxin in shelled peanuts and peanut products.

The Commissioner has considered promulgating the present proposal as an action level. Limiting an unavoidable aubstance through use of an action level, rather than a tolerance, is appropriate when changes are foreseeable in the near future that might affect the appropriateness of the limitation established. This, however, is not the case with aflatoxins. The Commissioner is unaware of any new or anticipated developments that would affect the proposed 15 ppb level in the near future. There are no new procedures pending, either agronomic or technical, that will alter the present unavoidability of aflatoxins. Furthermore, it is unlikely that any new pertinent information will become available in the near future.

Therefore, it is the Commissioner's preliminary conclusion that the most reasonable approach to regulating aflatoxin, in shelled peanuts and peanut products, would be a formal tolerance established under section 406 of the act. The Commissioner, however, specifically solicits comments on the question of whether any anticipated changes make an action level more appropriate.

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Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 306, 402, 406, 701, 52 Stat. 1045-1046 as amended, 1049, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 336, 342, 346, 371) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 122 be amended by adding a new § 122.101 as follows:

§ 122.101 Aflatoxin in shelled peanuts and peanut products used as human food.

(a) A tolerance of 15 parts per billion (ppb) is established for total aflatoxins (B_1, B_2, G_1, G_2) in shelled peanuts and peanut products used as human food.

(b) Compliance with this section shall be determined as follows:

(1) A lot shall consist of a collection of primary containers or units of the same size, type and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of common container code or marking, a day's production.

(2) (i) The sample for aflatoxin analysis of smooth peanut butter shall consist of a composition of 24 subsamples (primary units) randomly drawn from a lot.

(ii) For all other peanut products, the sample shall consist of a composite of 48 subsamples (primary units) randomly chosen from a lot, or if from a bulk lot, 48 1-pound subsamples.

(3) Composites shall be analyzed in duplicate using 50-gram portions from the lot sample by the methods of the Association of Official Analytical Chemists (AOAC), as described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., Chapter 26, Secs. 26.015-26.020.[1]

(4) A lot does not comply with the tolerance established in paragraph (a) of this section when:

(i) The average value of the two analyses of the composite of randomly chosen subsamples is greater than 15 ppb total aflatoxins; and

(ii) The identity of aflatoxins in the analytical sample is confirmed by chemical derivative formation (AOAC, Official Methods of Analysis, 11th Ed., Chapter 26, Secs. 26.054-26.055).

Interested persons may, on or before March 6, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 29, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc. 74-28408 Filed 12-5-74;8:45 am]

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

[4110 93]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 77N-0166]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

POISONOUS OR DELETERIOUS SUBSTANCES

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This rule establishes procedures for regulating food contaminants and naturally occurring poisonous or deleterious substances in food. This action is being taken to implement those provisions of the Federal Food, Drug, and Cosmetic Act that permit the Commissioner of Food and Drugs to set tolerances and action levels to control the levels of unavoidable contaminants in food. These procedures, which also permit the identification and listing of naturally occurring poisonous or deleterious substances in food, apply to all poisonous or deleterious substances in food, including food contact surfaces, pet food, and animal feed.

EFFECTIVE DATE: October 31, 1977.

FOR FURTHER INFORMATION CONTACT:

Caesar A. Roy, Bureau of Foods (HFF-310), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington. D.C. 20204 (202-245-1567).

SUPPLEMENTARY INFORMATION:

These regulations were proposed in the FEDERAL REGISTER of December 6, 1974 (39 FR 42746). Several comments were received in support of the proposed regulations; others supported the general approach but opposed specific provisions. The Commissioner's responses to most of the comments received are set forth below.

However, comments that concerned proposed § 122.7(c) of the regulations, which would codify the agency's prohibition against "blending" a food containing a poisonous or deleterious substance above the permitted tolerance with less contaminated food, have not yet been fully evaluated. The issue of "blending" remains under study within FDA, and the prohibition will not be codified at this time. Until the issue is resolved, the agency's long-standing prohibition against "blending" remains in effect.

When these regulations were proposed, regulations codified in 21 CFR Parts 121 and 122 (now Parts 109 and 170-189, recodification was published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) applied to food for human use as well as pet food and animal feed. Subsequently, regulations covering pet food and animal feed were recodified separately from the regulations covering human food. The pet food and animal feed regulations are now codified in 21 CFR Parts 509 and 570 (recodification from Parts 121 and 122 was published in the FEDERAL REGISTER of September 10, 1976 (41 FR 38618)). This document, therefore, establishes identical regulations in Parts 109 (food for human consumption) and 509 (pet food and animal feed). The changes in 21 CFR Part 181 were incorporated into Subchapter E for pet food and animal feed under 21 CFR 570.13.

1. Comments stated that FDA should never permit the sale of contaminated food.

The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities. This is not a modern phenomenon. Wholesome foods have inevitably been the carriers of levels of contamination beyond the capability of contemporary processing methods to eliminate and sometimes even detect. At best, therefore, specifications for "food grade" substances can be established, as has been done in the Food Chemicals Codex, to ensure that only minimal levels of contaminating substances are present. Where more significant levels of contamination occur unavoidably, action levels or tolerances may be established under Part 109 (formerly Part 122), of the regulations to ensure the safety of the food.

2. One comment suggested that the label of a contaminated food bear the warning "hazardous to health."

The Commissioner advises that tolerances and action levels will be established at levels intended to ensure that food marketed is not hazardous to health. The suggested warning would therefore be unnecessary and inappropriate. If any food is found to be hazardous to health, FDA will not permit it to be distributed in interstate commerce.

3. A number of comments argued that the distinction in the act between "added" and naturally occurring poisonous or deleterious substances is a distinction between substances introduced into the food chain through the agency of man and those introduced through the force of nature.

The Commissioner concludes that there is no basis for basing a distinction between "added" and naturally occurring contaminants on the presence or absence of human intervention. If that distinction were to be adopted as the proper interpretation of the statute, it would be necessary to ascertain the precise means by which a contaminant was

introduced into the environment, often in historic time, before taking regulatory action. It makes little sense to argue that a contaminant that was introduced into the environment by man generations ago should be regarded differently from contamination caused, for example, by geological phenomena, such as contamination of water by mercury. There would be regulatory problems in trying to ascertain the role human activity played in introducing a contaminant. For example, in the case of contamination occurring through mercury leaching into water from geological sources, it would presumably be necessary to determine whether man's activities exposed more geological surfaces to the waters than would naturally have been exposed. Such an expensive and protracted inquiry would provide no additional information upon which to determine the level of contamination that can be safely tolerated. Moreover, there is nothing in the statute that suggests that the definition of an "added" poisonous or deleterious substance is related to human involvement.

4. One comment contended that the language "any poisonous or deleterious substance added to any food" in section 406 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346) contemplates addition through the agency of man since the term "added" is "used as an active verb."

The Commissioner notes that the comment discussed only the initial portion of section 406 of the act. The section goes on to identify two circumstances in which "added" poisonous or deleterious substances may be permitted: (1) Where the substance is "required in the production" of a food, and (2) or where the substance "cannot be avoided by good manufacturing practice." Although the language of the first circumstance connotes human action, the language of the second does not.

5. One comment stated that the legislative history of the act demonstrated that the term "added" poisonous or deleterious substances referred to substances that became

a component of food through the agency of man. In support of this contention, the comment quoted from the testimony of Walter Campbell, then Chief of the Food and Drug Administration, who was concerned with contamination resulting from the "development of the country and the extension of industrial activities." The comment also emphasized Mr. Campbell's examples of smoke contaminating sugar with arsenic and pesticides spray residues in support of its argument that the concept of "added" poisonous or deleterious substances was limited to food contaminants introduced into the environment by man. The comment also cited a 1934 Senate committee report that stated that the amended statute covered all contaminants "whether that constituent is added by man or put there by nature." In addition, the comment emphasized language in the report that stated "it is immaterial to the welfare of the consumer whether a poison in his food is introduced by artifice or occurs naturally." The comment argued that this testimony and committee report support the conclusion that the term "added" poisonous or deleterious substance pertains only to those substances for which human activity is responsible.

The Commissioner concludes that the legislative history cited in the comment does not support the contention that "added" poisonous or deleterious substances are only those that become a component of food through the agency of man. Industrial development was seen as leading to the appearance of additional contaminants, but there is nothing in the legislative history to suggest that the often remote human connection with food contaminants was to be the basis for permitting tolerances to be established. It is implausible that Congress would have intended that, before establishing a tolerance, an inquiry into the source of a contaminant be made to determine whether human activity, perhaps generations earlier, may have set in motion events leading to the contamination.

The cited language in the committee report focused on the fact that naturally occurring poisons were being covered by the statue for the first time. Consequently, the casual reference to substances "added by man" is of limited significance, as it refers to an unchanged provision of the statute. Moreover, the reference to "added" substances as being those "introduced by artifice" connotes a concept different from contamination as a result of human activity.

6. One comment asserted that the few judicial decisions that have interpreted the statutory words "added" and "not * * * added" in the act do not support the definition established in the regulation. The comment claimed that "United States v. 1200 Cans, Pasteurized Whole Eggs," 393 F. Supp. 131 (N.D. Ga. 1972), was of limited precedential value because of parties stipulated that *Salmonella* in frozen eggs in an added poisonous or deleterious substance. Morever, the comment argued, *Salmonella* is not, like trace elements of natural origin in living organisms, a natural constituent of the host food, possessing potentially nutritional or other valuable properties at low levels and toxic properties at higher levels. The comment asserted that the case "United States v. 1,600,800 Pounds of White Corn," Civil No. T-4173 (D. Kan., Dec. 18, 1970), was distinguishable because the court found that there is no minimum or base line level of aflatoxin commonly found in foods. The comment argued that the Commissioner has ignored "United States v. 1232 Cases of American Beauty Brand Oysters," 43 F. Supp. 744 (W.D. Mo. 1942), which squarely held that shell fragments in cans of oysters are not "added" substances under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)).

The Commissioner advises that since publication of the proposed regulation, another court has interpreted the meaning of the term "added," a decision that supports the

Commissioner's position. In the "United States v. An Article of Food Consisting of Cartons of Swordfish," 395 F. Supp. 1184 (S.D.N.Y., 1975), the court stated:

> The government also contends that mercury in swordfish is an added substance within the meaning of 21 U.S.C. § 342(a)(1) * * *. According to the government, the test for determining whether a substance is added is whether it occurs naturally in the food * * *. We agree with the government's position on the point. We find unpersuasive claimant's argument that mercury could not be an added substance because it has been found in fish for centuries. Assuming this to be so, it adds nothing to the question of whether mercury is naturally produced by fish and thus whether it is an added substance within the meaning of the statute.

That *Salmonella* is entirely foreign to frozen eggs and aflatoxin entirely foreign to white corn do not diminish the precedential value of the decisions cited with respect to contaminants identical to naturally occurring components of an organism. It is wholly consistent with the principle of the decisions that any amount of a substance above that naturally occurring is "added" within the meaning of the act. This is the interpretation codified in proposed § 122.3(d), now § 109.3(d).

The Commissioner also believes that the case "United States v. 1232 Cases of American Beauty Brand Oysters" supports the regulations. The court in that case held that shell fragments were not "added" within the meaning of the act because they were, like fish bones, inherent in the food. The case supports the thrust of § 109.3(d) which is that the test of whether a substance is "added" is whether it is intrinsically part of the food.

7. One comment stated that living organisms contain a variety of naturally occurring trace elements whose precise biological role is unknown but whose presence at low levels may be essential. The comment contended that the definitions in the proposed regulation would expand the class of "added" poisonous or deleterious substances to encompass trace elements, such as heavy metals, absorbed by animal organisms from their natural environment.

The Commissioner advises that the distinction drawn in the act, and in the regulations, between "added" and naturally occurring poisonous or deleterious substances is between substances that are inherent and those that are not. If a trace element, such as a heavy metal, is essential to the biological function of an animal, then it is inherent to that animal and it is not to be regulated as an "added" substance, unless it has been increased above the natural level by environmental contamination. If a substance is absorbed from a contaminated environment, in greater than normal amounts, it is not appropriate to regard it as naturally occurring, but to regard it as a contaminant and to take any appropriate action necessary to protect the public health. Contrary to the comment, which argues that this distinction is illogical, the Commissioner finds irrational the belief that the act of biological absorption somehow renders a contaminant "natural". Nothing in the act, or in sound science, suggests that a contaminating substance should be treated specially because it is absorbed by a living organism, or because an organism naturally contains a trace amount of the same substance. The Commissioner's position was implicitly approved in the instance of fish absorbing DDT from the water by the court in "United States v. Ewig Bros. Co.", 502 F.2d 715 (7th Cir. 1974).

8. Comments stated that numerous scientific studies have demonstrated that the level of mercury in ocean fish has remained historically constant and that mercury in

marine fish is not primarily a result of manmade pollution but is of natural origin. The comment cited studies indicating that the mercury content of 90-year-old fish, museum specimens of fish caught between 25 and 93 years ago, and various prehistoric fish are of the same order of magnitude as the mercury content of living fish of the same species. The comments argued that since the level of mercury content of the fish has not changed over time, it should not be regarded as an "added" substance but rather as naturally occurring.

The Commissioner believes that the act does not contemplate treating a contaminant differently because it has persisted in the environment for a long time. If the comment's interpretation were correct, the validity of a tolerance for a persistent contaminant would eventually be placed in doubt on the ground that the passage of time has transformed the substance from "added" to naturally occurring even though the levels occurring pose the same risks to human health. Nothing in the act supports such a result. Moreover, the comment's position was specifically considered and rejected by the court in "United States v. An Article of Food Consisting of Cartons of Swordfish", discussed above.

9. One comment questioned whether, if a very substantial portion of a commodity contains, despite all efforts, some level of a mycotoxin, that mycotoxin is an "added" substance. The comment noted that "added" was defined in the regulations as encompassing all ingredients that are not inherent parts of a food, and stated that, under the conditions identified, it would seem that mycotoxins are not necessarily "added" substances. The comment stated that certain manmade substances such as pesticides have become a component of the environment and, like certain natural substances such as mycotoxins widely occurring in nature, would not seem always to be "added" substances within the meaning of the act.

This comment points up the problem of looking only to the current state of the environment to determine whether a substance in food is "added." Certain pesticides have become ubiquitous environmental contaminants and are found in nearly all food. Nevertheless, it is clear that such pesticides are not intrinsic parts of food and should not be regarded as such. The act does not contemplate that serious contamination should be subject to lesser controls than minor contamination, which would be the result if ubiquitous contaminants were "natural" while other, less universal contaminants were regarded as "added." The Commissioner therefore concludes that under the act the test for determining whether a substance is "added" or natural is whether it is necessarily an inherent part of food, in which case it is natural. Otherwise it is "added" under the law. Thus, in the example of mycotoxins suggested by comment, the inquiry is not whether all lots of the commodity contain mycotoxin contamination, but whether the mycotoxin is inherently part of the food. This approach will permit adequate control over contaminants, from whatever source, and is the approach contemplated by section 406 of the act.

10. One comment requested clarification of FDA's policy concerning "environmental contamination." The comment gave as an example that corn grown in South Dakota averaged 0.40 part per million (ppm) selenium, while corn grown in Indiana averages 0.04 ppm selenium. The comment stated that these differences are presumably due to differences in selenium content of the soil. The comment questioned whether the differences between 0.04 and 0.40 ppm is "added" selenium. The comment interpreted the regulations, in referring to environmental contamination, as treating increased levels of substances to be "added" only when the increase is caused by man.

The Commissioner does not agree with the comment's interpretation. A substance is "added" within the meaning of the statute when it is increased to abnormal levels through intervening circumstances; these need not involve human intervention, but could involve merely the kinds of geological processes that raise the concentration of a toxic trace element to unusually high concentration in a particular locality. If food may pose a risk to health because of the abnormally high mineral content of the soil in which it is grown, it is appropriate under the act that the Commissioner take action to protect the public health. To repeat, contamination of concern is in no way limited to that which can be attributed to man.

11. One comment stated that the reason we have poisons in our food is due mainly to governmental agencies that allow pesticides to enter the food chain. The comment stated that if farmers knew that the contaminated foods could not be marketed, they would use more natural methods to prevent crop destruction.

The Commissioner advises that the use of pesticides is regulated by the U.S. Environmental Protection Agency (EPA), which establishes conditions for their safe use and tolerance levels for residues resulting from such use. Nothing in these regulations would permit the sale of food that was contaminated beyond the established tolerance or action level or was contaminated through unlawful use of a pesticide or any other added substance except in the rare instance in which such contamination is of such magnitude that destruction of the food would constitute a substantial adverse impact on the national food supply and then only if the food itself is safe for consumption.

12. One comment requested clarification of the meaning of a "poisonous or deleterious substance." The comment stated that a substance may be beneficial or even essential at one level, and yet poisonous or deleterious at a higher level.

The language "poisonous or deleterious substance" appears in section 402(a)(2) of the act (21 U.S.C. 342(a)(2)), and it is not further defined. The Commissioner concludes that clarification of the term is not necessary for purposes of these regulations. The issue in an administrative proceeding to establish a tolerance or action level is the level necessary to protect the public health. Accordingly, it is unnecessary to specify in the abstract what constitutes a "poisonous or deleterious substance."

13. One comment stated that proposed § 122.6(b)(2) (now § 109.6(b)(2)), which provides that a tolerance will be established at a level "sufficient for the protection of the public health," fails to define what constitutes "sufficient" in terms of a margin of safety. The comment stated that if FDA plans to allow such margins, the regulations should so specify with particularity.

The Commissioner advises that it is not possible to specify in advance the margin of safety that will be used for any given contaminant. Particularly in the case of action levels, available data on safety may be so limited that it will be unclear what margin of safety is being provided. Nevertheless, it may be appropriate to establish an action level based on the little data that are available. Also, as was the case, for example, in the proposed action level for mercury in fish and shellfish (December 6, 1974, 39 FR 42738), the margin of safety may vary greatly depending upon how much of the food a particular individual consumes. So far as possible, a proposal to establish a tolerance and the supporting material on file with the Hearing Clerk in the case of an action level will provide information from which it may be concluded what margin of safety is being established. Comments could then address the question whether the margin is sufficient under the circumstances.

14. One comment questioned the language of proposed § 122.4(b) (now § 109.4(b)(1)) which states that an action level "may prohibit any detectable amount of the substance in food." The comment was concerned that nothing more was said about methodology in the regulations. The comment questioned whether the existence of an action level would be dependent upon a specifically approved method of detection.

The Commissioner advises that in establishing an action level or tolerance he will specify the method of detection that is to be used to ensure compliance with the tolerance or action level.

15. One comment referred to the language in proposed § 122.4(a) (now § 109.4(a)) that a tolerance may be established at the level of zero. The comment stated that "zero" depends upon the sensitivity of the method, and suggested that it would be more accurate to state that a tolerance may be established at "no detectable amount of the substance in the food."

The Commissioner agrees with the comment and has revised the regulation accordingly. The Commissioner advises that when a tolerance is established at the level of zero, a method of analysis will always be specified in the regulation establishing the tolerance.

16. One comment opposed proposed § 122.7(a) (now § 109.7(a)), which states that tolerances and action levels will be established at levels "based on the unavoidability of the poisonous or deleterious substance concerned." The comment asserted that section 406 of the act does not permit establishing a tolerance based on a substance's degree of unavoidability, but must be confined to toxicological aspects. The comment asserted that a potentially offending substance need not be eliminated from a class of foods where it is present at completely safe levels simply because it can be eliminated. The comment asserted that

FDA has a duty to permit theoretically avoidable but nevertheless safe levels of poisonous or deleterious substances.

The Commissioner advises that the standard of unavoidability established by section 406 of the act is whether the substance can be avoided by good manufacturing practice. If a substance can be avoided by good manufacturing practice, it is deemed by section 402(a)(2)(A) of the act to be unlawful at any level. If a substance cannot be avoided, the Commissioner is expressly directed by section 406 of the act to "take into account the extent to which the use of such substance * * * cannot be avoided" in the production of food. Therefore, the agency must consider the degree of unavoidability of a substance and not simply toxicological aspects.

17. Comments contended that the section on unavoidability (§ 122.7, now § 109.7) does not adequately define the term. The comments stated that adulteration is not unavoidable simply because all purveyors of a food product produce a similarly adulterated item. They stated that customary practice of the industry is not the measure of duty or due care, and that FDA should make clear in this section that objective capability, and not industry practice, defines unavoidability.

As noted above, the act defines an unavoidable substance as one that cannot be avoided by good manufacturing practice. The Commissioner agrees that an industry's customary practice does not necessarily constitute good manufacturing practice. Section 122.7 (now § 109.7) states that the manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible. However, the specific criteria for determining good manufacturing practice will vary. An attempt to define

particular circumstances in which an industry's practice does not constitute good manufacturing practice would be beyond the scope of these regulations.

18. Comments objected to the definition of "food" in proposed § 122.3(e) (now § 109.3(e)) because it is different from the definition of "food" in section 201(f) of the act. One comment asserted that indirect food additives, that is, substances migrating to food from food-contact articles, are not foods within the meaning of the definition of section 201(f).

The Commissioner advises that all food additives are "foods" under the law. Moreover, all substances migrating from food-contact surfaces are "foods" within the meaning of the act. This position has been upheld by the courts in *United States* v. *Articles of Food,* 370 F. Supp. 371 (E.D. Mich. 1974), and in *Natick Paperboard Corp.* v. *Weinberger,* 389 F. Supp. 794 (D. Mass. 1975), aff'd, 525 F.2d 1103 (1st Cir. 1975). Thus, the regulation simply clarifies the scope of the act for the benefit of the public and regulated industry. Under Part 109 a tolerance or action level may be established for an unavoidable contaminant of a packaging material or other food-contact article. For example, the existing (stayed) tolerance for polychlorinated biphenyls establishes a tolerance for their presence in paper packaging materials (21 CFR 109.30(a)(9), formerly 21 CFR 122.10(a)(9)).

19. One comment suggested that there should be different definitions for "food" and "feed" because in many instances the poisonous or deleterious substance in question should be treated differently depending on whether it is intended for human or animal consumption.

The Commissioner agrees that different tolerances or action levels may be established for human and animal food. These differences will be reflected in the individual tolerances or action levels established, where appropriate.

Changing the definition of "food" would not facilitate this approach, however, nor is it necessary to its implementation.

20. One comment stated that it is unrealistic to establish tolerances or action levels for contaminants that are equally applicable to human food and animal feeds. The comment stated that animal feeds and human food should be considered separately throughout the regulations.

As noted, the Commissioner agrees that it will often be appropriate to establish different tolerances or action levels for human food and animal feeds.

21. The proposed regulations provided for the establishment of action levels through informal (i.e., notice and comment) rule making. The Commissioner has reconsidered this aspect of the proposal, and for the reasons discussed below, concludes that an alternative procedure is preferable. The approach adopted will conserve limited FDA resources while preserving the opportunity for the public to comment upon any action level set and the scientific bases for the decision.

In the preamble to the proposal, the Commissioner stated that action levels, as opposed to tolerances under section 406 of the act, are appropriate in dynamic circumstances. Thus, an action level is appropriate if industrial practices are improving so quickly that the extent to which a substance is avoidable changes significantly from year to year, or if toxicological data are scanty or conflicting but additional data are being developed. The procedures required by section 406 of the act, including a public hearing and the requirement of substantial evidence to support a tolerance, contemplate ample evidence, and a relatively stable situation, in which any tolerance promulgated will be appropriate for a relatively long period of time.

There is an inherent conflict between the dynamic circumstances in which an action level is appropriate and the use of rule making to set such a level. Although the time required to set an action level through informal rule making is less than that required for a tolerance under section 406 of the act, establishment of action levels through informal rule making would still involve a substantial amount of time and agency resources. Because of the time required to promulgate an action level and the dynamic circumstances in which action levels are used, the possibility exists that an action level will be outdated soon after it is promulgated, in which case the process would have to begin anew. The potential for wasteful expenditure of agency resources has persuaded the Commissioner that a simplified procedure for adopting action levels should be used.

In so concluding, however, the Commissioner is mindful of the need to provide for public access to, and review of, the data on which FDA relies in setting an action level and for an opportunity to comment upon the level set. The bases and rationale for action levels cannot be shielded from the public if the agency's decisions are to be credible. In evaluating various alternative procedures for setting action levels, the Commissioner has given great weight to the extent to which specific alternatives would satisfy this need.

The Commissioner recognizes that the approach described below and adopted in § 109.4(b)(2) of the regulations may prove not wholly satisfactory. The Commissioner is committed to reviewing the procedure periodically and to proposing revisions if they appear to be appropriate.

Under § 109.4(b) of the regulations, when the agency sets an action level for a specific poisonous and deleterious substance, a notice will be published in the FEDERAL REGISTER announcing that fact. Before the notice is pub-

lished, the FDA will place on file with the Hearing Clerk all pertinent data and information regarding the substance, including FDA memoranda analyzing those data and discussing the rationale for the level that has been chosen. The notice will explicitly call attention to the material placed on file with the Hearing Clerk. Additionally, the notice will invite and specify a time for public comments on the level. FDA will review any comments received and, as part of the continuing process of reviewing action levels, modify any level if the comments warrant that action. Any interested person may petition the FDA to set a different action level under the procedures set forth in 21 CFR Part 10 (Subpart A of Part 2, prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)).

On occasion it may be necessary to set an action level to respond to any "emergency" situation. In such a case, a memorandum will be placed on file with the Hearing Clerk stating that an action level has been set. As soon as possible thereafter, a notice will be published in the FEDERAL REGISTER to the same effect.

Because of the dynamic circumstances in which action levels are used, it will frequently be necessary to revise a particular action level before a notice can be published in the FEDERAL REGISTER. A notice will be published as soon as possible whenever an action level is changed. The Commissioner anticipates that a notice will be published in the near future setting forth all existing action levels for poisonous and deleterious substances.

22. One comment questioned whether there is any authority or justification for section 406 tolerances for food additives that may be regulated under section 409 of the act. The comment asserted that food additives are entirely avoidable, as distinquished from the unavoidable contaminants with which section 406 of the act deals.

The Commissioner agrees in part with the comment. Tolerances under section 406 of the act (and action levels) should not be established in Part 109 for intentionally added food ingredients or for components of food-contact articles that serve a functional purpose in the food-contact article. Tolerances under section 406 of the act and action levels may be established only for contaminants of food or food-contact articles, such as the tolerances established for polychlorinated biphenyls unavoidably present in several classes of food and in paper-packaging materials (21 CFR 122.100, now 21 CFR 109.30). Such contaminants may include substances that are "food additives" within the meaning of the act if the substances are unavoidable in a particular food; this conclusion was fully discussed in the preamble to the proposed regulations.

The Food and Drug Administration may have occasion to establish an action level for an intentionally used food ingredient or for a functional component of a food-contact article. If questions arise about the safety of a substance that has long been used in food on the assumption that the substance was generally recognized as safe, it might be appropriate to issue an interim food additive regulation under § 180.1 (21 CFR 180.1) (formerly 21 CFR 121.4000) to permit the continued safe use of the substance while the questions are being resolved. However, it might also be appropriate to restrict use of the substance while the interim food additive regulation is being made final. In such a case an action level would be announced to establish the level at which FDA would take action against the substance under section 402(a)(2)(C) of the Act. An interim food additive regulation would be proposed as soon thereafter as practicable. The Commissioner has added a new paragraph (f) to § 180.1 to set forth the conditions under which such an action level may be considered. A similar paragraph has been added to

§ 181.1 (21 CFR 181.1) (formerly 21 CFR 121.2000) to identify the conditions under which an action level may be established for a prior-sanctioned substance. No action level would be established for an approved food additive, however; the procedure for changing the permitted conditions of use of an approved food additive is that prescribed in section 409 of the act.

The first action levels established for functional componets of food-contact articles are to control lead and cadmium migration from pottery and enamelware, lead migration from silver-plated hollowware, and lead migration from cans containing evaporated milk and skim milk to their contents. These action levels currently exist and will continue to be used.

23. Comments recommended that the circumstances described in § 122.8 (now § 109.8) under which an unlawfully contaminated food could be permitted to be marketed should not be as stringent as those circumstances in which there would be a "substantial adverse impact on the national food supply." The comments argued that it is conceivable that destruction of a single contaminated product could ever have such an impact and suggested that an exception be permitted whenever destruction of the food involved "would cause a needless waste of food and thus an unwarranted economic loss to the consuming public." Another comment suggested that the criterion should be whether the destruction or diversion of the food involved would "contribute to an adverse impact on the national food or feed supply."

The Commisioner concludes that it is not appropriate to sanction the essentially routine marketing of unlawfully contaminated food as was suggested by these comments. The act permits establishing tolerances and action levels for food that has been unavoidably contaminated. If, however, the food was at some stage of its production unlawfully (i.e., avoidably) contaminated, then the act

contemplates that such food shall ordinarily not be marketed. Consquently, the Commissioner concludes that such food should be permitted to be marketed only in the most extraordinary circumstances.

The proper functioning of the agency's regulatory program requires that unlawfully contaminated food ordinarily be destroyed to make unlawful action unprofitable. The fact that the present owner of the food may not have been responsible for the avoidable contamination is not a convincing reason for departing from this policy. To create an exception for persons who unknowingly purchase contaminated foods would permit persons engaged in illegal conduct to profit from their illegal actions. If unlawfully contaminated food were permitted to be sold, then its owner would have no cause of action for damages in a civil action against the person responsible for the contamination. The only action that could be taken against the person responsible for the contamination would be criminal prosecution, where the government is required to prove guilt beyond a reasonable doubt, and where the penalties imposed are likely to be small in relationship to the value of the goods. Consequently, the Commissioner concludes that it is necessary for proper enforcement of the act that unlawfully contaminated food ordinarily be seized and destroyed, notwithstanding the fact that it may be at the time of such destruction in the hands of an innocent party, and notwithstanding the fact it may on occasion be safe for consumption.

24. One comment sought clarification of § 109.8 which refers to "a substantial adverse impact on the national food supply" and stated that carload or warehouse lots of adulterated foods should not fall into this category. Another questioned whether the unavailability of one variety of fruit or vegetable would result in a "substantial adverse impact." Other examples posed included whether

a few pennies per week inflation in the price of food would constitute such an adverse impact and whether the bankruptcy of a major food company as a result of destruction or diversion of certain food would constitute a substantial adverse impact on the national food supply.

The Commissioner agrees that the loss of carload or warehouse lots of adulterated food would almost never have a substantial adverse impact on the national food supply. It would not be appopriate to examine and pass on all possible circumstances at this time, however. In accordance with § 109.8(a)(2), whenever possible an exemption will be issued only after opportunity for public comment.

25. One comment stated that, if unlawfully contaminated food is permitted to be sold in accordance with § 109.8, FDA should investigate the reason for the contamination and not exclude civil or criminal action against responsible individuals even though the food was sold.

The Commissioner agrees with this comment. Granting an exemption does not exempt from liability the person who unlawfully contaminated the food. The Food and Drug Administration would investigate and initiate appropriate regulatory action against persons responsible for unlawfully contaminated food, even if the food were permitted to be sold.

26. Comments objected to the provision in § 109.6(d) that applies when the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act (21 U.S.C. 371(e)(2)) by the filing of an objection. Under that section, the order establishing the tolerance is deemed to be an order establishing an action level until final action is taken upon the objection. Comments argued that if a hearing is requested, the reasonableness of the tolerance would be in doubt and that, therefore, its enforcement as an action level would not be justified. One comment suggested that a tolerance became an action level only in cases where a hazard to health is involved.

The Commissioner notes that if the substance that is the subject of the tolerance is a food additive, it is unlawful at a detectable level, under section 402(a)(2)(C) of the act (21 U.S.C. 342 (a)(2)(C)). Thus, if a tolerance is stayed by an objection, the presence of the substance is unlawful at any level, and regulatory action may be taken; an action level is appropriate to determine the level at which action should be taken. This approach was approved by the Court of Appeals in "Natick Paperboard Corp. v. Weinberger," cited above.

If the substance is not a food additive, but is an unavoidable "added" poisonous or deleterious substance, then action may be taken pursuant to section 402(a)(1) of the act, which remains applicable to a particular substance until a tolerance is in effect. Thus, for substances that are not food additives, a tolerance indicates the level at which the Commissioner will take action against a substance on the ground that the level may be injurious to health. The establishment of a tolerance does not make unlawful what would otherwise be lawful; it may, however, make lawful what would otherwise be unlawful.

The Commissioner rejects the suggestion that a tolerance stayed by an objection should become an action level only in cases where a hazard to health is involved. By hypothesis, in the case of poisonous or deleterious substances a potential hazard to health always exists, and that is the basis upon which action levels and tolerances are established.

27. One comment asserted that FDA may not avoid the procedures of section 406 of the act by establishing an action level. The comment stated that where Congress has specified with particularity the hearing procedures by which a certain administrative action may be taken, an agency is without authority to depart from the congressionally mandated process. The comment asserted that FDA is obligated to elect one of two courses: it must either disclaim any intent to attach the force of law to its action

levels, or it must adopt those action levels as tolerances under section 406 of the act and in accord with the procedures specified in section 701(e) of the act.

The Commissioner disagrees. As to those substances that would be illegal at any level in the absence of an action level, e.g., because they are food additives, the courts have upheld FDA's authority to issue action levels. Those cases were cited in the preamble to the proposed regulation. As to other substances, the act clearly contemplates that the Government may proceed against a contaminated food under section 402(a)(1) of the act when no tolerance is effective. Furthermore, in light of the procedure adopted for establishing action levels in the regulations, this point, for the present at least, is moot.

28. One comment included data and arguments concerning the tolerance for polychlorinated biphenyls.

The Commissioner notes that the tolerances for polychlorinated biphenyls were not proposed in the FEDERAL REGISTER of December 6, 1974, but were simply reprinted because the section number is being changed.

29. One comment stated that the republication of the tolerance for polychlorinated biphenyls in paper-packaging materials should state that the regulation is stayed.

The Commissioner agrees and has added an appropriate note.

30. One comment offered an interpretation of the proviso in section 402(a)(2)(C) of the act, which provides that a pesticide chemical present in a processed food is lawful if the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. The comment interpreted the term "ready to eat" as permitting a processed food to contain a higher concentration of pesticide than is permitted for the raw agricultral commodity if the food is "disbursed" in other food when consumed in a manner such that the

pesticide level of the mixture is below the tolerance. As an example, the comment cited dehydrated peppers, which contain pesticide residues greater than the tolerance for raw peppers because of the dehydration; the comment contended that the dehydration pepper was not "ready to eat" until it had been incorporated into a finished food and that the tolerance is properly applied to the entire finished food into which it was incorporated.

The Commissioner disagrees with the interpretation of the act offered by the comment. The term "ready to eat" does not permit compliance with a tolerance to be determined after the food has been mixed with other food; the term applies when a food is to be modified before use, e.g., by hydration.

One of the principal purposes for which a tolerance is established by regulation is to provide a readily ascertainable standard by which FDA and affected persons can determine whether a particular lot of food conforms to the requirements of the law. Under the interpretation suggested by the comment, there would be no definite standard to determine whether a particular lot of dehydrated peppers complies with the law. Instead, its legality would turn on uncertain subsequent events involving the manner in which the food was to be used. By contrast, foods that are not ready to eat because they must be modified in a particular way may be so modified prior to analysis, and compliance may thus be determined with certainty. In the event that processing increases the concentration of a pesticide, the act permits a tolerance to be established under section 409 of the act; this procedure permits a clear, enforceable limit and is the procedure to be followed.

31. The Commissioner has revised proposed § 109.4(b) to delete the reference to section 402(a)(1) of the act. This reference was inconsistent with § 109.6(c), which establishes the standards for an action level. The Commis-

sioner has also revised proposed § 109.6(d), which refers to the statutory authority for issuing tolerances and action levels, by explicitly stating the pertinent sections of the act.

32. The Commissioner has revised proposed § 109.6(a), to clarify the relationship of FDA and EPA in establishing tolerances and action levels for added poisonous and deleterious substances that are also pesticide chemicals. The regulations that EPA issues under sections 406, 408, and 409 of the act will establish tolerances; FDA will implement action levels under the criteria of these procedural regulations. Upon FDA's request, EPA will recommend an action level based on the criteria set forth in these procedural regulations.

33. The Commissioner advises that the prohibition in the regulations against marketing unlawfully contaminated food is not intended to change the agency's current policy permitting the diversion of contaminated human food into use as animal feed when such diversion would pose no significant risks to human or animal health. Proposed regulations will be published in the FEDERAL REGISTER to formally establish the permissible conditions for such diversion.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 406, 408, 409, 701(a), 52 Stat. 1045-1046 as amended, 1049 as amended, 1055, 68 Stat. 511-518 as amended; 72 Stat. 1785-1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371(a))) and under authority delegated to him (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. By revising Part 109 to read as follows:

PART 109—UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

Subpart A—General Provisions

Sec.

109.3 Definitions and interpretations.
109.4 Establishment of regulations.

109.5 Petitions.
109.6 Added poisonous or deleterious substances.
109.7 Unavoidability.
109.8 Exemptions.
109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

109.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

Subpart C—Naturally Occurring Poisonous or Deleterious Substances—[Reserved]

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045-1046 as amended, 1049 as amended, 1055-1056 as amended, 68 Stat. 511-518 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371).

Subpart A—General Provisions

§ 109.3 Definitions and interpretations.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes human food and substances migrating to food from food contact articles.

§ 109.4 Establishment of regulations.

(a) When appropriate under the criteria of § 109.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b)(1) When appropriate under the criteria of § 109.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define the level of contamination at which a food will be deemed to be adulterated. An action level may prohibit any detectable amount of the substance in food.

(2) Whenever an action level is established, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Hearing Clerk before the notice is published. The notice shall invite public comment on the action level. Regulatory action may be taken at any time after an action level is established, and need not await publication of the notice. An action level may be changed at any time if the protection of the public health so requires. A notice shall be published in the FEDERAL REGISTER as soon as practicable after an action level is changed.

(c) A regulation may be established in Subpart C of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 109.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 10.65 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 109.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under section 406, 408, or 409 by the U.S. Evironmental Protection Agency (EPA). When such a regulation has not been issued, an action level for added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Adminstration. The

Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under the authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the

order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

§ 109.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a) (4) of the act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

§ 109.8 Exceptions.

(a) The Commissioner may exempt from the regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a notice in the FEDERAL REGISTER and public comment shall be invited on

the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies, e.g., the specific growing area or other identifying information. The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a) (1) (i) of this section and promugated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

§ 109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of

lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contamination in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feed as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk, and eggs). Investigations by the Food and Drug Adiministration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's. The source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food-packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packing materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before September 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to made on an individual installation and operation basis.

(c) The provisions of this section do not aply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerance for Unavoidable Poisonous or Deleterious Substances

§ 109.30 Polychlorinated Biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufacturing dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements and feed premixes).

(6) 2 parts per milion in animal feed components of animal origin, including fishmeal and other by-products of marine origin, and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerences established in this section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

NOTE.—At 38 FR 22794, Aug. 24, 1973, the following appeared concerning § 109.30(a)(9) (formerly 122.10(a)(9)):

* * * § 109.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by § 109.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973, containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

2. By adding new paragraph (f) to § 180.1 to read as follows:

§ 180.1 General.

* * * * *

(f) Where appropriate, an emergency action level may be issued for a substance subject to paragraph (a) of this section that is not an approved food additive, pending the issuance of a final interim food additive regulation. Such an action level shall be issued pursuant to sections 306 and 402(a) of the act to identify, based upon available data, a safe level of use for the substance. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed interim food additive regulation. Where the available data do not permit establishing an action level

for the safe use of a substance, use of the substance may be prohibited. The identification of a prohibited substance may be made in Part 189 of this chapter when appropriate.

PART 181 – PRIOR-SANCTIONED FOOD INGREDIENTS

3. By adding new paragraph (c) to § 181.1 to read as follows:

§ 181.1 General.

* * * * *

(c) Where appropriate, an emergency action level may be issued for a prior-sanctioned substance, pending the issuance of the final regulation in accordance with paragraph (b) of this section. Such an action level shall be issued pursuant to section 402(a) of the act to identify, based upon available data, conditions of use of the substance that may be injurious to health. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed regulation in accordance with paragraph (b) of this section. Where the available data demonstrate that the substance may be injurious at any level, use of the substance may be prohibited. The identification of a prohibited substance may be made in Part 189 of this chapter when appropriate.

PART 509 – UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL

4. Part 509 is revised to read as follows:

Subpart A – General Provisions

Sec.

509.3 Definitions and interpretations.
509.4 Establishment of regulations.
509.5 Petitions.
509.6 Added poisonous or deleterious substances.
509.7 Unavoidability.
509.8 Exemptions.
509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B – Tolerances for Unavoidable Poisonous or Deleterious Substances

509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

Subpart C – Naturally Occurring Poisonous or Deleterious Substances – [Reserved]

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045-1046 as amended, 1049 as amended, 1055-1056 as amended, 68 Stat. 511-518 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371).

Subpart A – General Provisions

§ 509.3 Definitions and interpretations.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes pet food, animal feed, and substances migrating to food from food-contact articles.

§ 509.4 Establishment of regulations.

When appropriate under the criteria of § 509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b)(1) When appropriate under the criteria of § 509.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define the level of contamination at which a food will be deemed to be adulterated. An action level may prohibit any detectable amount of the substance in food.

(2) Whenever an action level is established, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Hearing Clerk before the notice is published. The notice shall invite public comment on the action level. Regulatory action may be taken at any time after an action level is established, and need not await publication of the notice. An action level may be changed at any time if the protection of the public health so requires. A notice shall be published in the FEDERAL REGISTER as soon as practicable after an action level is changed.

(c) A regulation may be established in Subpart C of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 509.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 10.65 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 509.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under section 406, 408, or 409 by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may

be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent of which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the

tolerance shall be deemed to be an order establishing an action level until the final action is taken upon such objection.

§ 509.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substances concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

§ 509.8 Exemptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption, and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a notice in the FEDERAL REGISTER and public comment shall be invited on the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies, e.g., the specific growing area or other identifying information. The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

§ 509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United State); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food-packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to pubic health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determined whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be give to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes):

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

NOTE: At 38 FR 22794, August 24, 1973, the following appeared concerning § 509.30(a)(9) (formerly § 122.10(a)(9)):

* * * § 509.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by § 509.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C—Naturally Occurring Poisonous or Deleterious Substances—[Reserved]

Effective date: These regulations shall become effective October 31, 1977.

Dated: September 23, 1977.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 77-28576 Filed 9-29-77; 8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 78N-0062]

AFLATOXIN-CONTAMINATED CORN

Limited Exemption From Blending Prohibition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document grants certain States a limited exemption from a blending prohibition. This exemption applies to aflatoxin-contaminated corn. The blended corn must not exceed an action level and may be used only in certain animal feed. This action is taken to avert a substantial adverse impact on the national food supply.

EFFECTIVE DATES: April 4, 1978; expiration date: This exemption shall remain in effect until January 1, 1979.

FOR FURTHER INFORMATION CONTACT:

Caesar A. Roy, Bureau of Foods (HFF-310), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1186.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration is establishing a limited exemption to its prohibition against blending a food (corn) containing a poisonous or deleterious substance (aflatoxin) in amounts above the tolerance or action level (20 parts per billion (20 ppb)) with less contaminated food to obtain a mixture within the tolerance or action level. This exemption applies to corn harvested in 1977 in the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Virginia. The blending must be done in accordance with a technically feasible plan approved by the FDA Regional Office in Atlanta, Ga., before blending operations begin. The exemption does not apply to corn that contains more than 20 ppb aflatoxin if the corn has been shipped in interstate commerce. The blended corn must not exceed the action level of 20 parts per billion (ppb) aflatoxin and must be used only for animal feed for mature poultry and swine, and mature, non-milk-producing beef cattle. This exemption does not apply to corn or mixed feeds used for rations for dairy animals, or starter rations for very young animals, or to corn for human consumption.

Corn that contains aflatoxin in excess of the established FDA action level of 20 parts per billion (ppb) is an adulterated food under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)). Use of an adulterated food as an ingredient in another food ordinarily causes the finished food to be deemed adulterated, even if the finished product itself does not violate an established tolerance or action level.

The action level for aflatoxin applies only to unavoidable contamination of corn. Intentional blending of a violation article with an uncontaminated article is wholly avoidable and not authorized by the action level. Any aflatoxin contamination that can be shown to have occurred as a result of inadequate postharvest drying or faulty storage will be considered avoidable and therefore, not authorized by the tolerance.

Section 509.8 (21 CFR 509.8), issued in the FEDERAL REGISTER of September 30, 1977 (42 FR 52822), provides for exemptions from established action levels if the Commissioner of Food and Drugs determines that (1) based on all available evidence, the food is safe for consumption, and (2) destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

The Commissioner has reviewed all available evidence concerning the safety of aflatoxin in feed corn and has determined that the limited exemption to permit blending established by this notice will not result in any perceivable increased risk to the health of mature poultry and swine and mature non-milk-producing beef cattle fed such corn, or to humans consuming edible tissues derived from those animals.

The Commissioner has determined that the destruction or diversion of corn that would be required by the continued prohibition of blending of the subject feed corn would result in a substantial impact on the national food supply.

Based on data recently compiled by FDA, over half the 1977 corn crop in parts of the Southeast United States (Alabama, Georgia, Florida, Mississippi, North Carolina, South Carolina, and Virginia) may exceed the 20 ppb ac-

tion level and thus may not be shipped in interstate commerce. Since it may be difficult for farmers in this area to find adequate suppliers of corn for use in feeding animals if the law is enforced fully, the Commissioner has determined that he will not recommend regulatory action for violation of the Federal Food, Drug, and Cosmetic Act with respect to blending of such corn for use as animal feed if conditions of this notice are met.

It is anticipated that permitting the blending of feed corn under the terms of the exemption from the 20 ppb action level stated in this notice will increase the marketable feed corn crop in the seven States where blending will be allowed. This increase may be as much as 111.4 million bushels, valued at 235.5 million dollars at current support prices.

FDA has advised the States in the southeastern United States that intrastate corn containing up to 100 ppb aflatoxin may safely be used for animal feed for mature poultry and swine, and mature, non-milk-producing beef cattle if the State can ensure that the corn will not be diverted to other uses. Some States have told FDA that they cannot monitor the use of the corn closely enough to ensure that the limitation is adhered to; FDA has then advised the State not to permit corn containing more than 20 ppb aflatoxin to be used for any purpose. The exemption stated in this notice requires that the corn contain no more than 20 ppb after blending rather than 100 ppb because FDA cannot monitor the flow of corn in interstate commerce to the extent necessary to ensure that the corn is used in accordance with the terms of the exemption. Permitting corn containing up to 100 ppb aflatoxin to be shipped in interstate commerce would present an unreasonable risk that the corn would be used to feed dairy animals or very young animals, or that it would be used for food for human consumption.

The Commissioner is not altering the agency's long-standing position that it is ordinarily unlawful to blend corn containing aflatoxin above the action level with less contaminated corn. But the Commissioner is permitting blending on a one-time basis only because of the severity of this emergency situation.

Therefore, the Commissioner gives notice pursuant to § 509.8 (21 CFR 509.8) of the following exemption from the action level for aflatoxin:

Notice of Exemption

(a) The Food and Drug Administration will not recommend regulatory action against corn containing aflatoxin for violation of the Federal Food, Drug, and Cosmetic Act with respect to blending of corn containing aflatoxin in excess of 20 ppb if all the following conditions are met:

1. The contaminated corn was harvested in 1977 in the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Virginia.

2. Aflatoxin contamination did not result from improper agricultural, storage, shippping, or manufacturing practices.

3. A technically feasible plan for blending has been approved by the FDA Regional Office in Atlanta, Georgia, before blending operations begin. It must be demonstrated that the blending plan can reasonably be expected to result in a finished lot of corn containing not more than 20 ppb of aflatoxin. The blending must be accomplished under Federal or State supervision, and the finished lot must be approved by Federal or State authorities before shipment in interstate commerce. It must be demonstrated to the satisfaction of the supervising Federal or State authority that the aflatoxin level of the blended lot is not above 20 ppb.

4. The aflatoxin-contaminated corn must not have been shipped in interstate commerce prior to FDA approval of the blending plan. (If the FDA were to approve blending of corn after shipment in interstate commerce, there would be an unacceptable risk that some persons might ship contaminated corn in interstate commerce and blend only if the contaminated shipments were detected by Federal or State authorities).

5. The corn containing aflatoxins in excess of 20 ppb is mixed with noncontaminated corn resulting in a mixture containing no more than 20 ppb total aflatoxins.

6. The blended lot must be offered for use only for animal feed for mature poultry and swine and for non-milk-producing beef cattle. It may not be used to feed dairy animals or very young animals, and it may not be used for human consumption.

(b) In all other cases, the existing 20 ppb action level for aflatoxin contamination will be applied.

Assessments of safety and impact on the national food supply, including references and supporting data upon which this notice is based, are on file with the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Public comment is invited on any or all aspects of this notice and the Commissioner's determinations herein. Comments may be sent to the Hearing Clerk (address above) and will be received while this notice remains in effect.

This notice will be in effect until January 1, 1979.

Dated: March 24, 1978.

JOSEPH P. HILE
Acting Commissioner,
Food and Drug Administration.

[FR Doc. 78-8586 Filed 3-29-78; 10:06 am]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE,
1146 19TH STREET, N.W.,
WASHINGTON, D.C. 20036, (202) 833-1730

PUBLIC CITIZEN, 1346 CONNECTICUT AVENUE, N.W.,
WASHINGTON, D.C. 20036, (202) 293-9142

LINDA S. BARDOT, 8531 FOREST STREET, ANNANDALE,
VIRGINIA 22003 (703) 978-2306

AND

LAURA A. ROGERS, 2730 WISCONSIN AVENUE, N.W.,
WASHINGTON, D.C. 20007, (202) 338-5608
PLAINTIFFS,

v.

JERE GOYAN, COMMISSIONER, FOOD AND DRUG
ADMINISTRATION, 5600 FISHERS LANE, ROCKVILLE,
MARYLAND 20852, DEFENDANT

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This action seeks a declaratory judgment and order enjoining a pattern of continuing violations of law in defendant's regulation of the interstate sale of corn adulterated with aflatoxin, a potent carcinogen.

JURISDICTION

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331.

PARTIES

3. Defendant Jere Goyan is Commissioner of the Food and Drug Administration ("FDA") and is responsible for administering the Federal Food, Drug and Cosmetic Act, which prohibits the sale of adulterated food in interstate commerce. 21 U.S.C. § 331(a).

4. Plaintiff Community Nutrition Institute ("CNI") is a non-profit public interest organization which promotes the formation of a sound food policy that serves the health needs of consumers at the community level. CNI has long been active in opposing the sale of foods containing unsafe additives and other ingredients, and in a letter to the defendant dated October 6, 1980, specifically opposed the FDA policies now challenged in this case. CNI is supported, in part, by annual contributions in the form of subscriptions from approximately 6,000 persons. CNI brings this action on behalf of its supporters and also its approximately 28 employees, most or all of whom consume corn and related corn products, and milk and meat from animals which consume corn as feed.

5. Plaintiff Public Citizen is a non-profit, public interest organization supported by annual contributions from approximately 40,000 persons. Its Health Research Group ("HRG") is engaged in research and advocacy to promote safe food and drugs, and it has long opposed the sale of aflatoxin-contaminated food products. In 1975 it submitted comments in response to FDA's proposal to lower the tolerance level for aflatoxin in peanuts. Public Citizen brings this action on behalf of its contributors and on behalf of its approximately 52 employees, most or all of whom consume corn and related corn products, and milk and meat from animals which consume corn as feed.

6. Plaintiff Linda S. Bardot is an employee of CNI. She and her family, which includes two children ages 8 and

5, regularly eat corn and foods containing corn meal, and also drink milk and eat poultry, beef and pork, which come from animals fed on corn.

7. Plaintfiff Laura A. Rogers regularly eats corn and foods containing corn meal, and also drinks milk and eats poultry, beef and pork, which come from animals fed on corn.

STATUTORY AND REGULATORY FRAMEWORK

8. Section 301(a) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. § 331(a), prohibits the interstate shipment of "adulterated food. Adulterated food is defined as, among other things, food containing "any poisonous or deleterious substance which may render it injurious to health." 21 U.S.C. § 342(a)(1).

9. Section 406 of the FDC Act, 21 U.S.C. § 346, provides that when a poisonous or deleterious substance cannot be avoided, the Secretary shall set a formal tolerance level for such substance by promulgating regulations limiting the quantity "to such extent as he finds necessary for the protection of public health."

10. FDA's regulations prohibit the mixing or "blending" of a food contaminated above the current tolerance level with another lot of food not so contaminated, and state that such blending renders the final food adulterated regardless of the contamination level of the final food. 21 C.F.R. § 110.99(d).

FACTS GIVING RISE TO PLAINTIFFS' CLAIMS FOR RELIEF

11. Aflatoxin is a poison produced by a natural mold which grows on corn and other agricultural products, particularly in certain states in the southeastern portion of the United States. Aflatoxin is among the most potent carcinogens known in laboratory animals. There are also

positive correlations between dietary aflatoxins and primary human liver cancer. There is no known level of aflatoxin exposure which is considered safe for humans.

12. Since the early 1960's, FDA has considered corn and other products contaminated with certain levels of aflatoxin to be adulterated within the meaning of the FDC Act. However, FDA's program for the control of aflatoxin exposure demonstrates systematic and continuing violations of the FDC Act, the Administrative Procedure Act, and FDA's regulations.

13. FDA has never established a formal tolerance level for aflatoxin contamination in agricultural products, as required by section 406 of the FDC Act. Instead, FDA has set an informal action level, which is an administrative determination, without notice and comment rulemaking, as to the level of aflatoxin contamination below which no regulatory action will be taken against a product. Since 1969, the action level for aflatoxin in agricultural products, whether sold for human consumption or for animal feed, has been 20 parts per billion (ppb).

14. In 1978, contrary to its own regulations, FDA permitted the blending of corn contaminated with levels of aflatoxin in excess of 20 ppb with corn not so contaminated, provided the final product contained less than 20 ppb of alfatoxin. While affirming its long-standing position that it is unlawful to blend adulterated corn with less contaminated corn to achieve a product within the action level, FDA nevertheless permitted, on what it characterized as a "one-time basis only," the interstate shipment of blended corn from various states for use as feed for certain animals. 43 F.R. 14122-14123 (April 4, 1978).

15. In the fall of 1980, FDA again permitted the blending of aflatoxin-contaminated corn, this time approving the shipment and the sale of blended corn containing up to 100 ppb aflatoxin, 5 times the previously

allowable limit, for use as feed for certain animals. FDA granted this approval by way of telegrams to the Agricultural Departments of the states of North Carolina, South Carolina and Virginia. FDA provided no notice or opportunity for comment on this action.

PLAINTIFFS' CAUSES OF ACTION

16. FDA's approval of aflatoxin in corn by use of an informal action level is contrary to section 406 of the FDC Act, 21 U.S.C. § 346, which provides that tolerances shall be established by rulemaking.

17. FDA's approval of the intentional blending of adulterated corn, containing aflatoxin in excess of its long-standing action level, with corn not so contaminated is contrary to its own regulations, 21 C.F.R. § 110.99(d), and to the FDC Act, which permits the establishment of tolerance levels for poisonous or deleterious substances, but only if those substances are unavoidably present in food. 21 U.S.C. § 346.

18. FDA's approval of a five-fold increase in the action level of aflatoxin-contaminated corn used as feed for certain animals constitutes the approval of the shipment in interstate commerce of adulterated food, contrary to the FDC Act, 21 U.S.C. §§ 331 and 342.

19. FDA's approval of the shipment of corn containing up to 100 ppb aflatoxin is arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law within the meaning of section 10(e) of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), in view of the unreasonable risk that humans will consume significantly increased amounts of aflatoxin either in the meat or milk from animals fed such corn, or in products manufactured from such corn.

20. FDA's approval of a five-fold increase in its long-standing action level for aflatoxin of 20 ppb without notice and opportunity for comment is contrary to the Administrative Procedure Act, 5 U.S.C. § 553.

21. Linda S. Bardot, Laura A. Rogers, and the members, supporters, and employees of CNI and Public Citizens are aggrieved by FDA's actions in that, as a result, they and their families will consume increased amounts of aflatoxin. CNI, Public Citizen and the individual plaintiffs have also been deprived of the opportunity to comment on FDA's actions and of the additional protections that the FDC Act provides with respect to the establishment of formal tolerance levels for poisonous and deleterious substances in food.

22. Unless enjoined by this Court, FDA will continue a pattern and practice of violations of law in the regulation of aflatoxin-contaminated corn and plaintiffs will continue to suffer the kind of harms described in paragraph 21.

WHEREFORE, plaintiffs seek an order from this Court:

a) declaring that FDA has acted in violation of the FDC Act, the Administative Procedure Act and its own regulations by:

i) approving certain levels of aflatoxin in corn by use of an informal action level, rather than setting a formal tolerance through rulemaking,

ii) approving the blending of aflatoxin-contaminated corn, and

iii) approving a five-fold increase in the action level for aflatoxin-contaminated corn for certain uses, without notice and opportunity for comment;

b) enjoining FDA from approving or permitting the shipment in interstate commerce of corn contaminated with more than 20 ppb aflatoxin pending completion of a formal rulemaking, or of corn which has been blended with such contaminated corn;

c) granting plaintiffs their costs and disbursements in this action; and

d) providing for such other relief as may be just and proper.

Respectfully submitted,

/s/
Diane B. Cohn

/s/
William B. Schultz

/s/
Alan B. Morrison

Suite 700
200 P Street, N.W.
Washington, D.C. 20036
(202) 785-3704

Attorneys for Plaintiffs

December 5, 1980

[Docket No. 80N-0520]

AFLATOXIN-CONTAMINATED CORN: LIMITED EXEMPTIONS FROM PROHIBITION OF INTERSTATE SHIPMENT AND BLENDING

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces that !imited exemptions have been granted to the State of North Carolina and South Carolina and the Commonwealth of Virginia from the Food and Drug Administration's (FDA's) prohibition of interstate shipment and blending of corn containing aflatoxin in excess of the agency's action level of 20 parts per billion (ppb). Corn containing up to 100 ppb aflatoxin may be shipped in interstate commerce under plans which were developed by the three States and approved by FDA. The plans assure that such corn does not contain more than 100 ppb aflatoxin and is not diverted for uses other than as feed for mature, nonlactating livestock and mature poultry. Blending of corn to achieve levels of no more than 100 ppb aflatoxin is permitted under certain controlled conditions. These exemptions were granted to avert a substantial adverse impact on the national food supply.

EFFECTIVE DATES: October 9, 1980—North and South Carolina; November 5, 1980—Virginia.

EXPIRATION DATE: The exemptions apply only to the 1980 corn crop in North Carolina, South Carolina, and Virginia, and shall remain in effect until January 1, 1982.

FOR FURTHER INFORMATION CONTACT: Taylor M. Quinn, Bureau of Foods (HFF-300), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1243.

SUPPLEMENTARY INFORMATION: In response to requests from the States of North Carolina and South Carolina and the Commonwealth of Virginia, FDA is establishing limited exemptions to its prohibition of interstate shipment and blending of corn containing aflatoxin above its action level of 20 ppb. These exemptions apply only to the 1980 corn crop harvested in the States of North Carolina and South Carolina and the Commonwealth of Virginia and allow the interstate shipment of corn containing up to 100 ppb aflatoxin to be used only for feed for mature, nonlactating livestock and mature poultry. These exemptions do not apply to corn or mixed feeds used for rations for lactating dairy animals, or starter rations for very young animals, or to corn for human consumption. Corn containing more than 20 ppb may be blended with less contaminated corn to achieve a total aflatoxin level of no more than 100 ppb.

Any food that contains aflatoxin in excess of 20 ppb (FDA Administrative Guidelines Manual, 7420.01 (5/15/79)) is considered by FDA to be adulterated under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act. (21 U.S.C. 342(a)(1)), and therefore may not be shipped in interstate commerce. Also, use of an adulterated food as an ingredient in another food causes the finished food to be deemed adulterated, even if the finished food itself does not violate an established action level.

The 20 ppb action level for aflatoxin applies only to unavoidable contamination of food. Thus, the intentional blending of a violative food with an uncontaminated food is not authorized by the action level.

FDA's regulations on unavoidable contaminants in animal food and food-packaging material, 21 CFR 509.8, provide for exemptions from regulatory action if the Commissioner of Food and Drugs determines that (1) based on all available evidence, the food is safe for consumption,

that is, a significant health hazard is not involved, and (2) destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

The agency has reviewed all available evidence concerning the effects on the health of animals consuming aflatoxin contaminated corn and humans consuming food derived from these animals. The agency has determined that the limited exemptions specified in this notice will not result in any adverse effects to the health of mature, nonlactating liverstock and mature poultry fed such corn, and will not pose a significant health hazard or even a significant increase in risk to humans consuming edible products derived from these animals.

The agency has determined that the destruction or diversin of corn that would be required by the continued prohibition of interstate shipment and blending of the subject feed corn would result in a substantial adverse impact on the national food suply.

In the **Federal Register** of April 4, 1978 (43 FR 14122) FDA established a limited exemption to its prohibition against blending corn containing aflatoxin above its action level of 20 ppb with less contaminated corn to achieve a mixture below 20 ppb. The exemption applied only to corn harvested in 1977 in the southeast United States and was granted to avert a substantial adverse impact on the national food supply. In the 1978 notice, FDA stated that it had advised the States in the southeastern United States that "intrastate corn containing up to 100 ppb aflatoxin may be used safely for animal feed for mature poultry and swine, and mature, non-milk-producing beef cattle" if the State could ensure that the corn would not be diverted to other uses. FDA explained that the exemption required that the corn contain no more than 20 ppb after blending rather than 100 ppb "because FDA cannot monitor the flow of corn in interstate commerce to the extent necessary

to ensure that the corn is used in accordance with the terms of the exemption. Permitting corn containing up to 100 ppb aflatoxin to be shipped in interstate commerce would present an unreasonable risk that the corn would be used to feed dairy animals or very young animals, or that it would be used for food for human consumption."

Analyses of samples of the 1980 corn crop from the States of North Carolina and South Carolina and the Commonwealth of Virginia reveal that aflatoxin contamination in those States is at least as great as, if not greater than, the aflatoxin contamination in the 1977 corn crop harvested in parts of the southeast United States. North Carolina, South Carolina, and Virginia, estimate that 63, 73, and up to 23 percent of their 1980 corn crop, respectively, may contain more than 20 ppb aflatoxin and therefore may not be shipped in interstate commerce for food or feed use.

As part of their requests for exemptions from the current action level of 20 ppb aflatoxin, North Carolina, South Carolina, and Virginia have submitted to FDA detailed control plans to ensure that corn containing up to 100 ppb alfatoxin when shipped in interstate commerce is not diverted for uses other than as feed for mature, nonlactating livestock and mature poultry. Accordingly, FDA has agreed to permit (1) the shipment in interstate commerce of corn from the 1980 crop and which contains up to 100 ppb aflatoxin when such corn is shipped in accordance with those plans and (2) the blending of corn to achieve levels of aflatoxin of up to 100 ppb when such blending is done under certain controlled conditions. FDA anticipates that permitting the interstate shipment and blending of corn under the terms of the exemptions stated in this notice will increase the marketable feed corn crop in North Carolina, South Carolina, and Virginia. This increase is estimated at 101.4 million bushels, valued at 319.5 million dollars at current market prices.

The agency has determined that it will not recommend regulatory action for violation of the Federal Food, Drug, and Cosmetic Act with respect to the interstate shipment of corn from the 1980 crop harvested in North Carolina, South Carolina, and Virginia and which contains no more than 100 ppb aflatoxin; or with respect to the blending of corn to achieve a level of no more than 100 ppb aflatoxin, provided the conditions set out in this notice are met. FDA emphasizes, however, that it is not altering the agency's longstanding positions that it is unlawful to ship in interstate commerce corn containing more than 20 ppb aflatoxin and that it is unlawful to blend corn containing more than 20 ppb aflatoxin with less contaminated corn and ship the blended corn in interstate commerce. The agency is permitting the exemptions set out in this notice on a one-time basis for the 1980 corn crop harvested in North Carolina, South Carolina, and Virginia only because of the severity of this emergency situation.

Therefore, the Commissioner gives notice pursuant to § 509.8 [21 CFR 509.8] of the following exemptions:

Notice of Exemptions

a. The Food and Drug Administration will not recommend regulatory action against corn from the 1980 corn crop harvested in North Carolina, South Carolina, and Virginia and which contains between 20 ppb and 100 ppb aflatoxin or corn blended to achieve a level of no more than 100 ppb aflatoxin for violation of the Federal Food, Drug, and Cosmetic Act, provided the following terms and conditions of plans submitted to FDA by the three States have been met:

1. All corn handled in the manner described in the States' plans shall be used only for feeding of mature, nonlactating livestock and mature poultry.

2. Upon notification by a firm of its intention to ship in interstate commerce corn containing between 20 ppb and 100 ppb aflatoxin, the State of origin's Department of Agriculture shall obtain from the intended shipper a history of the corn and shall collect samples of all lots of the corn.

3. The lot (i.e., individually-characterized mass of corn, compartmentalized and ready for shipment to purchaser) or corn shall either be stream-sampled at intervals during the entire loading process to obtain at least a ten-pound sample or randomly-sampled with appropriate-size commercial grain probes to obtain at least a ten-pound sample that is representative of the lot.

4. The entire sample shall be the ground, mixed, and analyzed by the State laboratories as prescribed in the "Official Methods of Analyzed of the Association of Official Analytical Chemists," 13th ed. 1980.

5. The test acceptance level for each lot shall be 80 ppb or less. For stream-sampled corn, a single analysis is sufficient; for randomly sampled corn, a duplicate analysis shall be performed, the average result of which may not exceed the 80 ppb level. Under this system, there is a 95 percent or greater probability that a lot of corn which contains a true mean of 100 ppb or more aflatoxin will be rejected.

6. Each lot of corn shall be labeled at all times with the name and address of the purchaser and of the seller, the aflatoxin content, and the phrase "To be fed only to nonlactating mature livestock and/or mature poultry". Any invoice and bill of lading shall also be marked with this information. In addition, the bill of lading shall bear the seal numbers or other identification to relate the bill of lading to the lot.

7. The Department of the Agriculture of the State of origin shall maintain records for a period of at least one year after obtaining the samples. Such records shall in-

clude, but not be limited to information showing: the origin of the corn, the date sampled, the aflatoxin content, the destination, how the corn shipped from the State of origin to the receiving State was controlled to prevent diversion (e.g., railcar seals), and the intended use of the corn at its destination.

8. The State of origin shall have a prearranged agreement with the appropriate regulatory agency in the State to which corn is to be shipped. This agreement shall specify the means by which the designated regulatory agency in the receiving State intends to assure proper disposition of the corn. As a part of the agreement, the receiving State shall written notification from each buyer (ultimate user) that the corn shall be fed only to mature nonlacting livestock or mature poultry. The State of origin shall also notify FDA of each lot of corn to be shipped and the destination of each lot. The receiving State shall agree to notify the State of origin and FDA when such shipments are received. The receiving State shall maintain records documenting the final and proper disposition of the corn by the ultimate user.

9. Before a lot of "blended" corn (i.e., corn which because of its high aflatoxin content has been mixed with other corn to reduce its aflatoxin content below 100 ppb) is shipped in interstate commerce, the responsible firm shall submit to the Department of Agriculture of the State of origin a plan that describes how uniform blending is to be accomplished, the aflatoxin content of the contaminated corn and the blended corn, methods to be used for sampling and analysis, and the moisture content of both lots of corn. The State Department of Agriculture shall review and, if appropriate, approve the plan, and notify the firm of any changes which must be made. The State Department of Agriculture shall forward a copy of the approved plan to the appropriate FDA Regional Office, and maintain records for inspection by FDA. The final lots shall be

sampled and analyzed by the Department of Agriculture of the State of origin as outlined in Steps 3 and 4 above and 11 below.

10. Corn in excess of 400 ppb aflatoxin shall not be used for blending.

11. Two ten-pound samples shall be randomly and representatively drawn from any lot of aflatoxin-contaminated corn which has been blended with other corn to achieve a level below 100 ppb aflatoxin. Both samples shall be analyzed in duplicate. The average of the duplicate analysis of the two ten-pound samples may not differ more than 50 ppb aflatoxin. The average four analysis may not exceed 80 ppb aflatoxin. If either of the assay criteria for blended corn is not met, the blending shall be classified as unacceptable. Reblending will be permitted.

12. Certification of the aflatoxin content of any lot of corn by the State or origin shall be made before interstate shipment.

13. Copies of the approved State plans for carrying out the FDA exemptions shall be distributed to all elevators merchandising corn in the affected States.

b. In all other cases the FDA's prohibition of interstate shipment and blending of corn containing aflatoxin in excess of the agency's 20 ppb action level will be applied.

All correspondence between the States of North Carolina and South Carolina and the Commonwealth of Virginia and FDA, including the State plans; and assessment of safety and impact on the national food supply, including references and supporting data upon which this notice is based, are on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

Public comment is invited on this notice and the Commissioner's determinations herein. Comments may be sent

to the Dockets Management Branch (address above) and will be received while this notice remains in effect.

This notice shall remain in effect until January 1, 1982.

Dated: January 19, 1981.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-2604 Filed 1-22-81; 8:45 am]

BILLING CODE 4110-03-M

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

JERE GOYAN, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEFENDANT.

ANSWER

First Defense

The Complaint fails to state a claim upon which relief may be granted.

Second Defense

This Court lacks jurisdiction over the subject matter of this action because the acts complained of are committed to agency discretion by law.

Third Defense

This Court lacks jurisdiction over the subject matter of this action because plaintiffs have failed to exhaust their administrative remedies.

Fourth Defense

This Court lacks jurisdiction over the subject matter of this action because none of the plaintiffs participated in a notice-and-comment rulemaking proceeding of the Food and Drug Administration ("FDA") which resulted in regulations that cover the acts about which plaintiffs complain.

Fifth Defense

Answering specifically the numbered paragraphs of the Complaint, using the same numbering, defendant states as follows:

1. Paragraph 1 contains plaintiffs' characterization of the action to which no response is required. To the extent an answer is deemed necessary, paragraph 1 is denied.

2. Paragraph 2 is denied because it consists of a conclusion of law.

3. Defendant admits that the Commissioner of Food and Drugs is responsible for administering the Federal Food, Drug and Cosmetic Act, but respectfully refers the Court to 21 U.S.C. § 331(a) for a complete and accurate statement of its contents. Defendant also admits that at the time this action was filed Jere Goyan was Commissioner of FDA.

4. Paragraph 4 is denied except to admit the receipt of the letter from plaintiff Community Nutrition Institute dated October 6, 1980. The denial of the other allegations in paragraph 4 is based on defendant's lack of knowledge sufficient to form a belief as to their truth.

5. Paragraph 5 is denied except to admit that in 1975 the Health Research Group submitted comments on FDA's "Proposed Tolerance; Aflatoxins in Shelled Peanuts and Peanut Products used as Human Food," 39 Fed. Reg. 42478 (December 6, 1974). The denial of the other allegations of paragraph 5 is based on defendant's lack of knowledge sufficient to form a belief as to their truth.

6-7. Defendant is without knowledge sufficient to form a belief as to the truth of the allegations of paragraphs 6 and 7. Paragraphs 6 and 7 are therefore denied.

8-10. Paragraphs 8, 9, and 10 are denied because they consist of conclusions of law. The Court is respectfully

referred to 21 U.S.C. §§ 331(a), 342(a)(1), 346, and 21 C.F.R. § 110.99(d) for a complete and accurate statement of their contents.

11. Defendant admits the first and second sentences of paragraph 11. With respect to the third sentence, defendant admits only that there are epidemiological studies which report positive correlations between dietary aflatoxins and primary human liver cancer. With respect to the fourth sentence, defendant admits only that there is no known level of aflatoxin exposure which has been proved to be safe for humans.

12. Defendant denied paragraph 12 except to admit that since the early 1960's, FDA has considered food containing aflatoxin in excess of certain amounts to be adulterated within the meaning of 21 U.S.C. §342(a)(1).

13. With respect to the first sentence of paragraph 13, defendant admits that FDA has never established, by regulations, a formal tolerance for aflatoxin in food, but denies that 21 U.S.C. §346 requires FDA to establish, by regulations, a formal tolerance for aflatoxin in food. The second and third sentences of paragraph 13 are admitted.

14. Paragraph 14 is admitted except to deny that the act complained of violated any FDA regulations. Defendant further states that the action taken was taken pursuant to and in accordance with 21 C.F.R. § 509.8.

15. Paragraph 15 is admitted except to deny that FDA provided no notice or opportunity for comment on the acts complained of. Defendant further states that notice and comment was provided for in 46 Fed. Reg. 7447-7449 (January 23, 1981). That notice expressly solicits comments on the exemptions which were granted pursuant to and in accordance with 21 C.F.R. § 509.8.

16-18. Paragraph 16, 17, and 18 are denied because they consist of conclusions of law. The Court is respectfully referred to the specific statutory and regulatory provisions cited for a complete and accurate statement of their contents.

19. Paragraph 19 is denied because it consists of conclusions of law. Further, defendant specifically denies the allegation that there is an unreasonable risk to humans or that humans will consume significant increased amounts of aflatoxin as a result of FDA's action. 46 Fed. Reg. 7447-49 (January 23, 1981).

20-22. Paragraphs 20, 21, and 22 are denied because they consist of conclusions of law.

The remaining portions of the Complaint contain plaintiffs' prayer for relief to which no response is required. To the extent a response is deemed necessary, the remaining portions of plaintiffs' Complaint are denied.

Any allegations not specifically admitted are hereby denied.

The defendant respectfully requests the Court to dismiss the action and grant the defendant his costs.

Respectfully submitted,

/s/
CHARLES F. C. RUFF
United States Attorney

/s/
ROYCE C. LAMBERTH
Assistant United States Attorney

/s/
PATRICIA J. KENNEY
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

JERE GOYAN, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEFENDANT.

DEFENDANT'S ANSWERS TO PLAINTIFFS' INTERROGATORIES

INTERROGATORY NO. 1

Identify all Federal Register notices, Code of Federal Regulations citations or other documents which propose or establish an action level for aflatoxin in food products.

ANSWER

i) February 15, 1965, Program Circular 16A-1 "Aflatoxin in Peanuts and Peanut Products."
ii) October 3, 1969 Memorandum from J. K. Kirk, FDA to Directors of Districts, FDA, "Aflatoxin in Peanuts and Peanut Products."
iii) The Federal Register of December 6, 1977 (42 FR 61630), *Aflatoxin Contamination of Milk*.
iv) FDA Administrative Guidelines Manual, 7412.01, Aflatoxin in Brazil nuts.
v) FDA Administrative Guidelines Manual, 7420.01, Aflatoxin in Foods and Feeds.

vi) FDA Administrative Guidelines Manual, 7406.06, Aflatoxin in Milk.
vii) FDA Administrative Guidelines Manual, 7412.03, Aflatoxin in Peanuts and Peanut Products.
viii) FDA Administrative Guidelines Manual, 7412.05, Aflatoxin in Pistachio Nuts.

FDA is diligently searching for any additional documents which are required under this interrogatory.

INTERROGATORY NO. 2

a) State whether the Food and Drug Administration ("FDA") has established a formal tolerance level for aflatoxin contamination in food. b) State whether FDA has ever considered the establishment of a formal tolerance level for aflatoxin in food, and, if so, identify all documents which reflect or refer to FDA's consideration of whether or not to set a formal tolerance.

ANSWER

2. a) No
b) FDA has considered the establishment of a formal tolerance for aflatoxin in peanuts. (See the Federal Register of December 6, 1974, 39 F.R. 42748; the Federal Register of March 3, 1978, 43 F.R. 8808).

INTERROGATORY NO. 3

List all tolerance levels for poisonous or deleterious substances established pursuant to 21 U.S.C. § 346 and identify all Federal Register or other documents or Code of Federal Regulations citations which establish such tolerance levels.

ANSWER

3. Tolerances for polychlorinated biphenyls (PCB's) in animal feeds, foods, and food-packaging materials were established July 6, 1973 (38 F.R. 18096):

i) 2.5 ppm in milk (fat basis).
ii) 2.5 ppm in manufactured dairy products (fat basis).
iii) 5 ppm in poultry (fat basis).
iv) 0.5 ppm in eggs.
v) 0.2 ppm in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).
vi) 2 ppm in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.
vii) 5 ppm in fish and shell fish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.
viii) 0.2 ppm in infant and junior foods.
ix) 10 ppm in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

The tolerance for PCB's in several classes of food were changed by Final Rule, June 29, 1979 (44 F.R. 38330):

i) 1.5 ppm in milk (fat basis).
ii) 1.5 ppm in manufactured dairy products (fat basis).
iii) 3 ppm in poultry (fat basis).
iv) 0.3 ppm in eggs.
v) 2 ppm in fish and shellfish (edible portion).

The tolerances for PCBs in paper food-packaging materials intended for or used with human food, finished

animal feed, and any components intended for animal feeds were stayed on August 24, 1973 (38 F.R. 22794) pending full review of the objections and request for hearing.

The tolerance for PCBs in fish and shellfish was stayed until further notice on October 5, 1979 (44 F.R. 57389).

INTERROGATORY NO. 4

List all action levels set with respect to any substances in food and identify all Federal Register notices or other documents or Code of Federal Regulations citations which establish such action levels.

ANSWER

4. Defendant objects to this interrogatory on the ground that it is not reasonably calculated to lead to the discovery of admissible evidence because the actions complained about in this case deal solely with aflatoxin in corn. Rule 26(b), Federal Rules of Civil Procedure. Information concerning FDA action levels for other substances in other foods is irrelevant and cannot lead to admissible evidence. Insofar as an answer to this interrogatory is deemed to be required, and without waiving its objection, FDA has attached a list (see exhibit 1) of all action levels for poisonous and deleterious substances in food. Defendant further objects to the identification of all Federal Register notices or other documents or Code of Federal Regulation citations which establish such action levels on the ground that such identification is not capable of leading to the discovery of admissible evidence and is unduly burdensome because the information regarding the Federal Register notices or Code of Federal Register citations and the custody of the "other documents" is widely dispersed throughout the agency and there is no one individual or group of individuals who possess this information.

INTERROGATORY NO. 5

For each application which has ever been made to the FDA for permission to ship corn which contains aflatoxin at levels in excess of 20 ppb or which has been blended, provide the following information:

a. identify the application and state who submitted it;

b. describe the terms of the approval requested, including the geographic area to which it would apply, the duration of the shipments, and the level of aflatoxin for which approval was sought;

c. the date the application was made;

d. the percentage of the crop for which the application was made which contained aflatoxin at levels in excess of 20 ppb;

e. what action the FDA took with respect to the application, and the reasons for such action; and

f. identify all documents which reflect, refer or relate to the information provided above, including, but not limited to, documents which reflect each application and the FDA's action in response to it.

ANSWERS

5. In 1978 (see 43 F.R. 14122) FDA established a limited exemption to its prohibition against blending corn containing aflatoxin above its 20 ppb action level with less contaminated corn to achieve a mixture below 20 ppb when the corn had not first been shipped in interstate commerce and was to be used only in certain animal feed. In 1980 (see 46 F.R. 7447), FDA agreed, if certain conditions were met, to not recommend regulatory action against corn which contains between 20 ppb and 100 ppb aflatoxin or which has been blended with corn containing in excess of 20 ppb to achieve a level of no more than 100 ppb aflatoxin if, *inter alia*, the corn is used only for feeding

mature, nonlactating livestock and mature poultry. To date, FDA has not received any applications, pursuant to the above exemptions, for permission to ship corn which contains aflatoxin at levels in excess of 20 ppb or which has been blended.

INTERROGATORY NO. 6

State whether blending has ever been approved for any food or other substance other than corn containing aflatoxin and, if so, identify all documents reflecting an application for blending authority and FDA's approval.

ANSWER

6. FDA has stated that it would not recommend regulatory action against lots of corn containing aflatoxin which had blended under certain conditions. (See 43 F.R. 14122; 46 F.R. 7447). FDA has never approved blending for any other food or any other substance.

INTERROGATORY NO. 7

Describe the amount of aflatoxin which remains in the tissue of mature, non-lactating animals which are fed corn containing a) 20 ppb aflatoxin, and b) 100 ppb aflatoxin. c) Identify all documents, articles, or other materials relied on to support the figures cited. d) Identify all documents, articles or other materials which dispute or disagree with the figures cited.

ANSWER

7. a) No detectable amount of aflatoxin remains in the tissues of mature, non-lactating animals which are fed corn containing 20 ppb aflatoxin and FDA therefore does not know what amount, if any, is present in the tissue of said animals.

b) No detectable amount of aflatoxin remains in the tissue of mature, non-lactating animals which are fed corn containing 100 ppb aflatoxin and FDA therefore does not know what amount, if any, is present in the tissue of said animals. As explained at page 6 of the "Aflatoxin-Contaminated Corn limited exemptions from prohibition of interstate shipment and blending—Assessments of Safety and Impact on the Nation Food Supply," Food and Drug Administration, December 1980, (Assessment) (Attached as Exhibit 2) an 800:1 feed tissue ration for swine does indicate that residues might be detected in swine liver when aflatoxin levels exceed 80 ppb in the animal's total ration. However, because corn is usually fed with other ingredients, the aflatoxin levels in the total swine ration will be lower than in the corn alone. Accordingly, aflatoxin residues in the liver from the total ration are not expected to exceed the 0.1 ppb level of detection.

c) The documents, articles, or other materials relied on to support the answers to 7a and 7b above are referred to in the Assessment, references 1-16.

d) Defendant is unaware of any documents, d) Defendant is unaware of any documents, articles, or other materials which dispute or disagree with the figures cited in 7a and 7b above.

INTERROGATORY NO. 8

Identify any regulation which establishes the method of examination approved by the Secretary of Health and

Human Services or other person for measuring the amount of aflatoxin which is found in the tissues of livestock or poultry fed aflatoxin-contaminated corn.

ANSWER

8. No such regulation has been established by the Secretary or any other person in the Department of Health and Human Services.

INTERROGATORY NO. 9

a) Identify all documents, articles, or other materials which support FDA's conclusion that corn containing up to 100 ppb aflatoxin can be safely fed to mature, non-lactating livestock and poultry, with no significant risk to human consumption of the animals fed such corn. b) Identify all documents, articles, or other materials which dispute or negate the conclusion that corn containing up to 100 ppb aflatoxin can safely be fed to mature, non-lactating livestock or poultry, with no significant risk to human consumption of the animals fed such corn. c) Explain the basis for FDA's conclusion that corn containing up to 100 ppb aflatoxin cannot be approved for feed for young or lactating animals or for human consumption.

ANSWER

9. a) See answer 7c for documents relied on by FDA. Other documents, articles or other materials which support FDA's conclusion that corn containing up to 100 ppb Aflatoxin can be safely fed to mature, non-lactating livestock and poultry with no significant risk to humans who consume animals fed such corn exist, but FDA objects to having to provide such a list on the ground that it is unduly burdensome for FDA to locate *all*

documents, articles, or other materials which support its position, especially when the documents relied on by FDA are available for public inspection at the FDA Documents Management Branch.

b) Defendant is unaware of any documents, articles or other materials which dispute or negate the above conclusion.

c) The basis for FDA's conclusion that corn containing up to 100 ppb Aflatoxin cannot be approved for feed for young or lactating animals or for human consumption is explained in the Assessment, pp. 4-7.

INTERROGATORY NO. 10

Explain the basis for FDA's establishment of a 20 ppb action level for aflatoxin-contamination in corn.

ANSWERS

10. Aflatoxin is a toxic chemical compound produced by the common molds aspergillus flavus. The initial action level for aflatoxin in foods (including corn) was set at 30 ppb in 1965. This level was subsequently lowered to 20 ppb in 1969. At the time they were established, the basis for these action levels was the lowest level at which the presence of aflatoxin could be demonstrated with sufficient certainty to support a court action, using prevailing practical analytical methology. See also a paper entitled, "*Aflatoxin Control: Past and Present*," presented by Mr. Leonard Stoloff of the United States Food and Drug Administration at a symposium on "Toxicity and Food Safety" at the ISF-AOCS World Congress, New York, N.Y., April 28, 1980 (attached as Exhibit 3).

INTERROGATORY No. 11

Identify the statutory basis for 21 C.F.R. § 509.8(a)(1), which permits an exemption from regulatory action when the Commissioner finds that destruction of a food would result in substantial adverse impact on the food supply.

ANSWER

The Federal Food, Drug, and Cosmetic Act, Sections 306, 402, 406, and 701, 21 U.S.C. 336, 342, 346 and 371.

INTERROGATORY NO. 12

Identify all documents which relate to or formed the basis for FDA's statement in 1978 that "permitting corn containing up to 100 ppb aflatoxin to be shipped in interstate commerce would present an unreasonable risk that the corn would be used for food for human consumption." 43 F.R. 14123 (April 4, 1978).

ANSWER

12. No particular document or set of documents formed the basis for the statement quoted in Interrogatory No. 12. That statement was based upon two factors: FDA's belief that it did not have the resources to adequately monitor and control interstate shipments of corn to assure that no corn containing in excess of 20 ppb would not be diverted for use for feed for young animals, dairy animals, or for human food; and the States' representations to FDA that they could not monitor the corn closely enough to ensure that the limitation was adhered to. The FDA has located the following documents which relate to the statement by FDA quoted in Interrogatory No. 12:

i) August 30, 1977 telegram from Donald Kennedy, Commissioner, FDA to Tommy Irvin, State of Georgia.
ii) September 1, 1977 FDA Talk Paper, "Aflatoxin in Corn."

i) September 7, 1977 telegram from G. Bryan Patrick, State of South Carolina to Taylor Quinn, FDA.
iv) September 8, 1977 telegram from Taylor Quinn, FDA to G. Bryan Patrick, State of South Carolina.
v) September 9, 1977 telegram from Taylor Quinn, FDA to C. J. Sullivan, State of Alabama.
vi) September 9, 1977 telegram from Taylor Quinn, FDA to James A. Graham, State of North Carolina.
vii September 23, 1977 telegram from Glenn W. Kilpatrick, FDA to Robert M. Reeves, State of Tennessee.
viii October 5, 1977 letter from Howard R. Roberts, FDA to W. E. McDomel, State of Delaware.
ix) October 14, 1977, FDA Talk Paper, "Aflatoxin in Southeast: General Update."
x) November 3, 1977 letter from Donald Kennedy, Commissioner, FDA to W. Y. Cobb, State of North Carolina.

INTERROGATORY NO. 13

a) Explain the basis for FDA's conclusion that, contrary to its determination in 1978, the interstate shipment of corn containing up to 100 ppb aflatoxin would no pose a risk of use for human consumption in 1980, and explain why the factors relied on to reach this conclusion were not present in 1978. b) Identify all documents which dispute, support, or are in any way relevant to the issue of whether the interstate shipment of corn containing up to 100 ppb aflatoxin would pose a risk that the corn would be used for human consumption.

ANSWER

13. a) As stated in the Federal Register of January 23, 1981 (46 FR 7447) the FDA did not permit corn

containing more than 20 ppb aflatoxin to be shipped in interstate commerce in 1978 because "some states have told FDA that they cannot monitor the use of the corn closely enough to ensure that the limitation is adhered to" and "because FDA cannot monitor the flow of corn in interstate commerce to the extent necessary to ensure that the corn is used in accordance with the terms of the exemption." In 1980, the States of North and South Carolina and the Commonwealth of Virginia submitted to FDA detailed control plans to ensure that corn containing up to 100 ppb aflatoxin when shipped in interstate commerce is not diverted for uses other than as feed for mature, non-lacting livestock and mature poultry (46 F.R. at 7447-7448). These control plans were not submitted to FDA in 1978 and therefore FDA decided to allow only corn containing up to 20 ppb aflatoxin to be shipped in interstate commerce.

i) August 28, 1980 letter from Mr. G. Bryan Patrick, State of South Carolina to Mr. Joseph P. Hile, FDA.
ii) September 12, 1980 telegram from Joseph P. Hile, FDA to Mr. G. Bryan Patrick, Jr., State of South Carolina.
iii) August 29, 1980 letter from James A. Graham, State of North Carolina to Mr. Joseph P. Hile, FDA.
iv) September 9, 1980 mailgram from Mr. James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.
v) September 12, 1980 telegram from Joseph P. Hile, FDA to James A. Graham, State of North Carolina.

vi) September 18, 1980 telegram from James A. Graham, State of North Carolina to J. P. Hile, FDA.
vii) September 19, 1980 letter from Bryan Patrick, State of South Carolina, to Mr. Joseph P. Hile, FDA.
viii) October 10, 1980 letter from James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.
ix) October 8, 1980 telegram from Joseph P. Hile, FDA to G. Bryan Patrick, Jr., State of South Caroiina.
x) September 19, 1980 letter from James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.
xi) September 25, 1980 memorandum of meeting, subject—aflatoxin in 1980 corn crop.
xii) October 8, 1980 telegram from Joseph P. Hile, FDA to James A. Graham, State of North Carolina.
xiii) October 9, 1980 telegram from North Carolina Department of Agriculture Commissioner James A. Graham to J. P. Hile, FDA.
xiv) October 28, 1980 letter from Commonwealth of Virginia to Mr. Joseph P. Hile.
xv) October 17, 1980 telegram from Mr. Joseph P. Hile, FDA to the States of Texas. Oklahoma, Arkansas, Louisiana, Mississippi, Alabama, Tennessee, Kentucky, Georgia, Florida, South Carolina, North Carolina, Virginia, Maryland and Delaware.
xvi) October 29, 1980 telegram from Mr. Joseph P. Hile, FDA to Mr. S. Mason Carbaugh, Commonwealth of Virginia.
xvii) October 31, 1980 letter to Mr. S. Mason Carbaugh from Taylor M. Quinn, FDA.

xviii) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to S. Mason Carbaugh, Commonwealth of Virginia.

xix) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to G. Bryan Patrick, Jr., State of South Carolina.

xx) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to James A. Graham, State of North Carolina.

INTERROGATORY NO. 14

State whether FDA viewed the aflatoxin contamination of the corn crop in the southeastern portion of the United States to be more severe in 1980 than in 1978 and, a) if so, describe the basis for this conclusion, b) if not, state why FDA approved the shipment of corn containing up to 100 ppb aflatoxin in 1980, but not in 1978.

ANSWER

14. a) As stated in the Federal Register of January 23, 1981 (46 FR 7447), "Analyses of samples of the 1980 corn crop from the States of North Carolina and South Carolina and the Commonwealth of Virginia reveal that aflatoxin contamination in those states is at least as great as, if not greater than, the aflatoxin contamination in the 1977 corn crop harvested in parts of the southeast United States. North Carolina, South Carolina, and Virginia, estimate that 63, 73 and up to 23 percent of their 1980 corn crop, respectively, may contain more than 20 ppb aflatoxin." Also, data from other Southeastern states indicates there may be a problem with aflatoxin contamination of 1980 harvested corn for the entire region which may result in requests from other states for similar exemptions. (See Assessment, p. 9).

INTERROGATORY NO. 15

Describe what monitoring actions FDA has taken to determine whether corn containing aflatoxin in excess of 20 ppb is being diverted to uses designed for human consumption.

ANSWER

15. No requests for the interstate shipment of corn containing aflatoxin in excess of 20 ppb have been received under the limited exemptions notice (see the Federal Register of January 23, 1981 (46 F.R. 7447)); therefore no monitoring of such blending or interstate shipment has taken place. FDA District Offices have continued normal surveillance and compliance activities with respect to corn products in conjunction with the surveillance and compliance activities of and, with the various states involved, will monitor and enforce compliance with the exemptions.

INTERROGATORY NO. 16

State whether the states of North Carolina, South Carolina and Virginia have, since 1978, acquired improved enforcement and monitoring capabilities to assure that corn containing up to 100 ppb aflatoxin is not used for human consumption, and identify all documents which relate or refer to this issue.

ANSWER

16. Yes. See Answer to Interrogatory No. 13, the Federal Register of January 23, 1981, (46 F.R. 7448-49) and the following documents on file with the Dockets Management Branch, at 80N-0520, Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857:

i) September 19, 1980 letter from Bryan Patrick, State of South Carolina, to Mr. Joseph P. Hile, FDA.
ii) October 8, 1980 telegram from Joseph P. Hile, FDA to G. Bryan Patrick, Jr., State of South Carolina.
iii) September 19, 1980 letter from James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.
iv) October 8, 1980 telegram from Joseph P. Hile, FDA to James A. Graham, State of North Carolina.
v) October 28, 1980 letter from Commonwealth of Virginia to Mr. Joseph P. Hile.
vi) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to S. Mason Carbaugh, Commonwealth of Virginia.
vii) October 24, 1980 letter from John Bass, State of South Carolina to Taylor Quinn, FDA.
viii) October 21, 1980 letter from Bryan Patrick, State of South Carolina to unaddressed.
ix) October 22, 1980 Memorandum from John A. Bass, State of South Carolina to Bill Whitely, Truluck Kelly, and C. T. Smith.
x) October 21, 1980 letter from Bryan Patrick, State of South Carolina to South Carolina Grain dealers.
xi) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to G. Bryan Patrick, Jr., State of South Carolina.
xii) October 10, 1980 letter from James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.

xiii) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to James A. Graham, State of North Carolina.
xiv) January 28, 1981 memorandum from Richard Moats, FDA to HFO-1.
xv) January 30, 1981 memorandum from Richard Moats, FDA to Acting Executive Director of Regional Operations, FDA.
xvi) February 2, 1981 telegram from Leonard F. Blanton, State of North Carolina to Richard Moats, FDA.
xvii) February 6, 1981 letter from A. D. Dell'Aria, Commonwealth of Virginia to Gentlemen.
xviii) February 6, 1981 inter-office Correspondence from Paul Ferrara, State of South Carolina to Bill Southall.
xix) February 1, 1981 telegram from Truluck Kelly, State of South Carolina to Richard Moats, FDA.

INTERROGATORY NO. 17

a) Identify all states which could receive corn shipped from North Carolina, South Carolina and Virginia and state whether they have, since 1978, acquired improved enforcement and monitoring capabilities to assure that corn containing up to 100 ppb aflatoxin is not used for human consumption. b) Identify all documents which refer or relate to this issue.

ANSWER

17. a) Any of the 49 other states "could" receive corn shipped from North Carolina, South Carolina and Virginia. Defendant is without knowledge to answer the second part of 17a but can state that the States of North Carolina, South

Carolina, and the Commonwealth of Virginia submitted control plans in 1980 which were not submitted in 1978 and which require states receiving corn from these states to comply with certain requirements to protect against unauthorized diversion of corn containing in excess of 20 ppb in order to receive corn shipped in interstate commerce pursuant to these exemptions.

b) See Answer 16.

INTERROGATORY NO. 18

List, describe and give the date of all instances of known or suspected violations of FDA's action levels and other policies regulating the interstate shipment of corn which have occurred since September, 1979.

ANSWER

18. The following list describes all instances of known or suspected violations of FDA's action levels and other policies regulating the interstate shipment of corn containing aflatoxin which have occurred since September, 1979. In many cases the corn from which these samples were collected had not moved in interstate commerce and therefore was outside of FDA's jurisdiction.

Corn Samples Collected and Found to Contain Aflatoxin Levels Above 20 ppb

Shelled Corn

Sample Number	*Collecting District*	*Collection Date*
0228859	Atlanta	9/22/80
0104654	Baltimore	9/5/80
0210319	Dallas	11/20/79
0222479	Houston	5/14/80
0221222	New Orleans	11/6/79
0221225	New Orleans	11/6/79
0228856	Nashville	9/15/80
0228857	Nashville	9/15/80
0228858	Nashville	9/15/80
0229467	Nashville	9/18/80
0229468	Nashville	9/18/80
0229469	Nashville	9/18/80
0229470	Nashville	9/18/80
0229471	Nashville	9/18/80
0229472	Nashville	9/18/80
0235750	Nashville	9/19/80
0235751	Nashville	9/19/80
0235752	Nashville	9/19/80
0268104	Orlando	9/17/80
0268106	Orlando	9/24/80
0268107	Orlando	9/24/80
0268108	Orlando	9/24/80
0268109	Orlando	9/24/80
0268110	Orlando	9/24/80
0268111	Orlando	9/24/80
0167226	Orlando	12/13/79
FY 81 To Date		
81163873	Atlanta	11/5/80
81260882	Houston	10/31/80
81237341	Atlanta	11/17/80

FY 81 To Date

Sample Number	*Collecting District*	*Collection Date*
81206575	Baltimore	10/8/80
81206579	Baltimore	10/16/80
81260034	Houston	10/28/80
81181511	Houston	12/16/80
81122136	New Orleans	11/18/80
81229482	Nashville	11/25/80
81235359	Nashville	11/19/80
81275624	Nashville	11/19/80
81223660	Philadelphia	10/14/80
81235658	Nashville	12/22/80
81235738	Nashville	11/4/80
81235377	Nashville	11/21/80
81275632	Nashville	12/16/80
81230296	Atlanta	1/19/81

Corn, Meal or Ground

FY 80

0221223	New Orleans	11/06/79
0230085	Atlanta	9/9/80
0230083	Atlanta	9/9/80
0238681	Atlanta	2/1/80
0238575	Atlanta	1/29/80

FY 81 To date

81163874	Atlanta	11/5/80
81236840	Atlanta	10/31/80
81237342	Atlanta	11/17/80
81237344	Atlanta	11/25/80
81163874	Atlanta	11/5/80
81236839	Atlanta	10/31/80
81248084	Chicago	10/16/80

City of Washington)
) ss
District of Columbia)

Taylor Quinn, being first duly sworn, deposes and says that he is Associate Director for Compliance, Bureau of Foods, United States Food and Drug Administration, Rockville, Maryland; that in such capacity he answers the above interrogatories, and, that the answers are to his best knowledge and belief true, although the truth of each of said answer is not known to him personally.

/s/
TAYLOR QUINN

Subscribed and sworn to before me this 6th day of March, 1981, in the City and District aforesaid.

/s/
NOTARY PUBLIC

My commission expires:
August 31, 1981

EXHIBIT 1

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

Action levels for poisonous or deleterious substances are established by the Food and Drug Administration (FDA) to control levels of contaminants in human food and animal feed.

The action levels are established and revised according to criteria specified in Title 21, *Code of Federal Regulations*, Parts 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective.

Action levels and tolerances represent limits at or above which FDA will take legal action to remove adulterated products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant.

Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contaminations, where it is avoidable. The blending of a food or feed containing a substance in excess of an action level or tolerance with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

This booklet lists action levels established by the FDA for poisonous or deleterious substances in human food and animal feed. The list is current as of July, 1980. Notices will be published in the *Federal Register* as new action levels are established or as existing action levels are revised or revoked. It is the responsibility of the user of the list to keep up to date on changes in the action levels.

Single copies of this list are available from:

Food and Drug Administration
Industry Programs Branch
Bureau of Foods (HFF-326)
200 C Streets, S.W.
Washington, D.C. 20204
Phone (202) 245-1523

FDA ACTION LEVELS

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*Indicates revisions since September 1, 1979.

AFLATOXIN

Commodity	*Action Level*	*Reference*
Brazil nuts	20.0 mcgs/kg	AG 7412.01
Foods and feeds	20.0 mcgs/kg	AG 7420.01
Milk	0.5 mcgs/kg (aflatoxin M_1)	AG 7406.06
Peanuts & peanut products	20.0 mcgs/kg	AG 7412.03
Pistachio nuts	20.0 mcgs/kg	AG 7412.05

ALDRIN & DIELDRIN

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at a level below 0.3 ppm for nonfatty foods and 0.3 ppm for fish and for milk.

ALDRIN & DIELDRIN—Continued

Commodity	*Action Level*	*Reference*
Animal feed, processed	0.03 ppm	AG 7426.04-A
Artichokes	0.05 ppm	AG 7420.08-A
Eggs	0.03 ppm	AG 7420.08-A
Fats & oils: animal, vegetable fish (animal feed)	0.3 ppm	AG 7426.04-A
Fish and shellfish	0.3 ppm	AG 7420.08-A
Pigs	0.05 ppm	AG 7420.08-A
Hay (animal feed)	0.03 ppm	AG 7426.04-A
Melons[1]	0.15 ppm	AG 7420.08-A
Milk and dairy products	0.3 ppm (fat basis)	AG 7420.08-A
Small fruits[1,2]	0.05 ppm	AG 7420.08-A
Sugarbeet pulp (animal feed)	0.1 ppm	AG 7426.04-A

[1]Other than those commodities specified in 40 CFR 180.135 and 180.137.

[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

BENZENE HEXACHLORIDE (BHC)

The figures below are for residues of total BHC. However, in adding amounts of individual isomers do not count alpha, gamma or delta BHC at a level below 0.1 ppm in milk or eggs and below 0.02 in other products. Do not count beta BHC at a level below 0.2 in milk or eggs and below 0.04 in other products.

Commodity	*Action Level*	*Reference*
Animal feed, processed	0.1 ppm	AG 7426.04-B
Barley, grain (animal feed)	0.1 ppm	AG 7226.04-B
Barley, grain (human food)	0.1 ppm	AG 7420.08-B
Beans	0.5 ppm	AG 7420.08-B
Citrus fruit[2]	0.5 ppm	AG 7420.08-B
Cocoa beans, whole raw bean	0.5 ppm	AG 7420.08-B
Corn, fresh sweet	0.5 ppm	AG 7420.08-B
Corn, grain (animal feed)	0.1 ppm	AG 7426.04-B
Corn, grain (human food)	0.1 ppm	AG 7420.08-B
Eggs	0.5 ppm	AG 7420.08-B
Endive	0.5 ppm	AG 7420.08-B
Figs	0.5 ppm	AG 7420.08-B
Frog legs	0.5 ppm	AG 7420.08-B

BENZENE HEXACHLORIDE (BHC)—Continued

Commodity	*Action Level*	*Reference*
Guavas	0.5 ppm	AG 7420.08-B
Hays (animal feed)	0.1 ppm	AG 7426.04-B
Mangoes	0.5 ppm	AG 7420.08-B
Milk and dairy products	0.3 ppm (fat basis)	AG 7420.08-B
Milo, sorghums (animal feed)	0.1 ppm	AG 7426.04-B
Milo, sorghums (human food)	0.1 ppm	AG 7420.08-B
Oats, grain (animal feed)	0.1 ppm	AG 7426.04-B
Oats, grain (human food)	0.1 ppm	AG 7420.08-B
Peas	0.5 ppm	AG 7420.08-B
Pineapples	0.5 ppm	AG 7420.08-B
Quinces	0.5 ppm	AG 7420.08-B
Root vegetables[2]	0.5 ppm	AG 7420.08-B
Rice, grain	0.1 ppm	AG 7420.08-B
Rye, grain (animal feed)	0.1 ppm	AG 7426.04-B
Rye, grain (human food)	0.1 ppm	AG 7420.08-B

BENZENE HEXACHLORIDE (BHC)—Continued		
Commodity	*Action Level*	*Reference*
Small fruits[1, 2]	0.5 ppm	AG 7420.08-B
Turnip greens	0.5 ppm	AG 7420.08-B
Wheat, grain (animal feed)	0.1 ppm	AG 7426.04-B
Wheat, grain (human food)	0.1 ppm	AG 7420.08-B

[1]Other than those commodities specified in 40 CFR 180.146.
[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

CADMIUM		
Commodity	*Action Level*	*Reference*
Pottery (ceramics) Flatware (ave. of 6 units)	0.5 mcgs/ml of leaching solution	AG 7417.02
Small holloware (any one of 6 units)	0.5 mcgs/ml of leaching solution	AG 7417.02
Large holloware (any one of 6 units)	0.25 mcgs/ml of leaching solution	AG 7417.02

CHLORDANE		
Commodity	*Action Level*	*Reference*
Animal fat, rendered	0.8 ppm	AG 7426.04-D
Animal feed, processed	0.1 ppm	AG 7426.04-D
Fish	0.3 ppm	AG 7420.08-L

CROTOLARIA SEEDS (C. spectabilis and/or C. striata)		
Commodity	*Action Level*	*Reference*
Grains and Feeds	Average of 1 whole seed/pound	AG 7426.03

DIBROMOCHLOROPROPANE		
Commodity	*Action Level*	*Reference*
Milk, raw, unpasteurized	1.5 ppm (fat basis)	AG 7420.08
Raw agricultural commodities (except milk)	0.05 ppm	AG 7420.08

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DDT, DDE, AND TDE

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of DDT, DDE and TDE do not count any of the three found below 0.2 ppm for fish, eggs, and grain.

Commodity	*Action Level*	*Reference*
Animal feed, processed	0.5 ppm	AG 7426.04-
Barley, grain (animal feed)	0.5 ppm	AG 7426.04-
Barley, grain (human food)	0.5 ppm	AG 7420.08-

DDT, DDE, AND TDE—Continued

Commodity	*Action Level*	*Reference*
Cocoa beans, whole raw bean	2.0 ppm	AG 7420.08-
Corn, grain (animal feed)	0.5 ppm	AG 7426.04-
Corn, grain (human food)	0.5 ppm	AG 7420.08-
Eggs	1.5 ppm	AG 7420.08-
Fish	5.0 ppm	AG 7420.08-
Hay	0.5 ppm	AG 7426.04-
Milo (sorghum), grain (animal feed)	0.5 ppm	AG 7426.04-
Milo (sorghum), grain (human food)	0.5 ppm	AG 7420.08-
Oats, grain (animal feed)	0.5 ppm	AG 7426.04-
Oats, grain (human food)	0.5 ppm	AG 7420.08-
Rice, grain (animal feed)	0.5 ppm	AG 7426.04-
Rice, grain (human food)	0.5 ppm	AG 7420.08-
Rye, grain (animal feed)	0.5 ppm	AG 7426.04-
Rye, grain (human food)	0.5 ppm	AG 7420.08-
Wheat, grain (animal feed)	0.5 ppm	AG ???????
Wheat, grain (human food)	0.5 ppm	AG ????????

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ENDRIN		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.03 ppm	AG 7426.04-F
Asparagus	0.05 ppm	AG 7420.08-E
Beans	0.05 ppm	AG 7420.08-E
Citrus fruits[2]	0.05 ppm	AG 7420.08-E
Corn, fresh sweet	0.05 ppm	AG 7420.08-E
Eggs	0.03 ppm	AG 7420.08-E
Figs	0.05 ppm	AG 7420.08-E
Fish and shellfish	0.3 ppm	AG 7420.08-E
Fish meal, fish solubles, fish oil (animal feed)	0.3 ppm	AG 7426.04-F
Guavas	0.05 ppm	AG 7420.08-E
Leafy vegetables[1,2]	0.05 ppm	AG 7420.08-E
Mangoes	0.05 ppm	AG 7420.08-E
Melons	0.05 ppm	AG 7420.08-E
Milk and dairy products	0.3 ppm (fat basis)	AG 7420.08-E
Oilseed meal, peanut, soybean, cottonseed, etc. (animal feed)	0.03 ppm	AG 7426.04-F

ENDRIN—Continued		
Commodity	*Action Level*	*Reference*
Okra	0.05 ppm	AG 7420.08-E
Peas	0.05 ppm	AG 7420.08-E
Pimentoes	0.05 ppm	AG 7420.08-E
Pineapples	0.05 ppm	AG 7420.08-E
Pome fruits[2]	0.05 ppm	AG 7420.08-E
Pumpkins	0.05 ppm	AG 7420.08-E
Root vegetables[1,2]	0.05 ppm	AG 7420.08-E
Small fruits[2]	0.05 ppm	AG 7420.08-E
Stone fruits[2]	0.05 ppm	AG 7420.08-E
Vegetable oils and fats, including soapstock (animal feed)	0.3 ppm	AG 7426.04-F

[1]Other than those commodities specified in 40 CFR 180.131.
[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

FENTHION		
Commodity	*Action Level*	*Reference*
Ground red peppers	0.3 ppm	AG 7420.08-F

HEPTACHLOR AND HEPTACHLOR EPOXIDE		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.03 ppm	AG 7426.04-G
Artichokes	0.05 ppm	AG 7420.08-G
Asparagus	0.05 ppm	AG 7420.08-G
Beans, except snap beans	0.05 ppm	AG 7420.08-G
Citrus fruits[2]	0.05 ppm	AG 7420.08-G
Cucumbers	0.05 ppm	AG 7420.08-G
Dairy products (manufactured) except low fat dairy products[1]	0.3 ppm	AG 7420.08-G
Eggs	0.03 ppm	AG 7420.08-G
Eggplant	0.05 ppm	AG 7420.08-G
Figs	0.05 ppm	AG 7420.08-G
Fish and shellfish	0.3 ppm	AG 7420.08-G
Leafy vegetables	0.05 ppm	AG 7420.08-G

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HEPTACHLOR AND HEPTACHLOR EPOXIDE – Continued		
Commodity	*Action Level*	*Reference*
Hays[1]	0.03 ppm	AG 7426.04-G
Melons	0.05 ppm	AG 7420.08-G
Okra	0.05 ppm	AG 7420.08-G
Pears	0.05 ppm	AG 7420.08-G
Pimentoes	0.05 ppm	AG 7420.08-G
Pumpkins	0.05 ppm	AG 7420.08-G
Quinces	0.05 ppm	AG 7420.08-G
Rice, grain, (animal feed)	0.03 ppm	AG 7426.04-G
Rice, grain (human food)	0.03 ppm	AG 7420.08-G
Small fruits[1, 2]	0.05 ppm	AG 7420.08-G
Stone fruits[1, 2]	0.05 ppm	AG 7420.08-G
Squash (summer or winter)	0.05 ppm	AG 7420.08-G

[1] Other than those commodities specified in 40 CFR 180.104 and 180.319.
[2] Refer to 40 CFR 180.34(f) for commodities covered by this food group.

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KELTHANE [1,1 Bis (p-chlorophenyl)-2,2,2,-trichloroethanol]		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.5 ppm	AG 7426.04-H

KEPONE [Decachlorooctahydro-1,3,4-methano-2H-cyclobuta (cd) pentalen-2-one]		
Commodity	*Action Level*	*Reference*
Crabmeat	0.4 ppm	AG 7420.08-H
Fish	0.3 ppm	AG 7420.08-H
Shellfish	0.3 ppm	AG 7420.08-H

LEAD		
Commodity	*Action Level*	*Reference*
Pottery (ceramics) Flatware (ave. of 6 units)	0.7 mcgs/ml of leaching solution	AG 7417.03
Small holloware (any one of 6 units)	5.0 mcgs/ml of leaching solution	AG 7417.03

LEAD – Continued		
Commodity	*Action Level*	*Reference*
Large holloware (any one of 6 units)	2.5 mcgs/ml of leaching solution	AG 7417.03
Silver-plated hollowware (ave. of 6 units)	7.0 mcgs/ml of leaching solution if product intended for use by adults	AG 7417.01
Silver-plated hollowware (one or more of 6 units)	0.5 mcgs/ml of leaching solution if product intended for use by infants and children	AG 7417.01

LINDANE		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.1 ppm	AG 7426.04-I
Artichokes	0.5 ppm	AG 7420.08-I
Barley (animal feed)	0.1 ppm	AG 7426.04-I
Barley (human food)	0.1 ppm	AG 7420.08-I
Beans	0.5 ppm	AG 7420.08-I
Citrus fruits[2]	0.5 ppm	AG 7420.08-I

LINDANE – Continued		
Commodity	*Action Level*	*Reference*
Cocoa beans, whole raw bean	0.5 ppm	AG 7420.08-I
Corn, fresh sweet	0.5 ppm	AG 7420.08-I
Corn, grain (animal feed)	0.1 ppm	AG 7426.04-I
Corn, grain (human food)	0.1 ppm	AG 7420.08-I
Eggs	0.5 ppm	AG 7420.08-I
Endive	0.5 ppm	AG 7420.08-I
Figs	0.5 ppm	AG 7426.08-I
Hays	0.1 ppm	AG 7426.04-I
Milk and dairy products	0.3 ppm (fat basis)	AG 7420.08-B
Milo (sorghum), grain (animal feed)	0.1 ppm	AG 7420.04-I
Milo (sorghum), grain, (human food)	0.1 ppm	AG 7420.08-I
Oats, grain (animal feed)	0.1 ppm	AG 7420 04-I
Oats, grain (human food)	0.1 ppm	AG 7420.08-I
Peas	0.5 ppm	AG 7420.08-I
Rice, grain (animal feed)	0.1 ppm	AG 7426.04-I
Rice, grain (human food)	0.1 ppm	AG 7426.08-I
Root vegetables[1, 2]	0.5 ppm	AG 7420.08-I
Rye, grain (animal feed)	0.1 ppm	AG 7426.04-I

LINDANE – Continued		
Commodity	*Action Level*	*Reference*
Rye, grain (human food)	0.1 ppm	AG 7420.08-I
Small fruits[1, 2]	0.5 ppm	AG 7420.08-I
Turnip greens	0.5 ppm	AG 7420.08-I
Wheat, grain (animal feed)	0.1 ppm	AG 7426.04-I
Wheat, grain (human food)	0.1 ppm	AG 7420.08-I

[1]Other than those commodities specified in 40 CFR 180.133.
[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

MERCURY		
Commodity	*Action Level*	*Reference*
Fish, shellfish, crustaceans, other aquatic animals. Edible portion only. Fresh, frozen or processed	1.0 ppm	AG 7408.09
Wheat (pink kernals only)	1.0 ppm	AG 7404.04

METHYL ALCOHOL		
Commodity	*Action Level*	*Reference*
Imported brandy	0.35%	AG 7401.01

MIREX		
Commodity	*Action Level*	*Reference*
Fish	1.0 ppm	AG 7420.08-J

NITROSODIMETHYLAMINE (NDMA)		
Commodity	*Action Level*	*Reference*
Malt Beverages	.5 ppb	CPG 7101.06

PARALYTIC SHELLFISH TOXIN		
Commodity	*Action Level*	*Reference*
Claims (fresh, frozen, canned)	80 ug/100 g meat	AG 7408.04
Mussels (fresh, frozen, canned)	80 ug/100 g meat	AG 7408.04
Oysters (fresh, frozen, canned)	80 ug/100 g meat	AG 7408.04

POLYBROMINATED BIPHENYLS (PBB's)		
Commodity	*Action Level*	*Reference*
Milk & dairy product (fat basis)	0.3 ppm	"A Review of Congressman William M. Brodhead's Petition to Reduce FDA's Action Levels for Polybrominated Biphenyls (PBB) In Food", July 27
Meat (fat basis)	0.5 ppm	
Eggs	0.05 ppm	
Animal Feed	0.05 ppm	

POLYCHLORINATED BIPHENYLS (PCB's)		
Commodity	*Action Level*	*Reference*
Paper food-packaging material intended for or used with human food, finished animal feed & and components intended for animal feeds	10 ppm	21 CFR 109.30(a)(9) and 509.30(a)(9) Tolerance stayed on 8-24-73 (38 FR 22794) 21 CFR 109.6(d) and 509.6(d)
Red Meat	3 ppm (fat basis)	CPG 7111.02

TOXAPHENE		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.5 ppm	AG 7426.04-M
Artichokes	1.0 ppm	AG 7420.08-K
Asparagus	1.0 ppm	AG 7420.08-K
Cherries	1.0 ppm	AG 7420.08-K
Figs	1.0 ppm	AG 7420-08-K
Fish	5.0 ppm	AG 7420.08-K
Melons	1.0 ppm	AG 7420.08-K
Mustard greens	1.0 ppm	AG 7420.08-K
Plums	1.0 ppm	AG 7420.08-K
Pumpkins	1.0 ppm	AG 7420.08-K
Root vegetables[1, 2]	1.0 ppm	AG 7420.08-K
Small fruits[1, 2]	1.0 ppm	AG 7420.08-K
Squash (summer or winter)	1.0 ppm	AG 7420.08-K
Turnip greens	1.0 ppm	AG 7420.08-K

[1]Other than those commodities specified in 40 CFR 180.138.

[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEFENDANT.

STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE DISPUTE

Pursuant to Rule 1-9(h) of the Rules of this Court, plaintiffs submit that there is no genuine issue as to the following material facts:

1. Aflatoxins are a group of chemically related substances produced by molds which can grow on corn and other agricultural products. Complaint ¶ 11; 39 F.R. 42748 (Dec. 6, 1974).

2. Aflatoxins are a potent liver carcinogen in laboratory animals. Complaint ¶ 11; 39 F.R. 42748 (Dec. 6, 1974).

3. There are epidemiological studies which report positive correlations between dietary aflatoxins and primary human liver cancer. Complaint ¶ 11; 39 F.R. 42748 (Dec. 6, 1974).

4. Since the 1960's, FDA has considered corn and other products contaminated in excess of certain amounts of aflatoxin to be adulterated within the meaning of the Food, Drug and Cosmetic (FDC") Act. Compaint ¶ 12.

5. In 1965, FDA established an action level for aflatoxin contamination in food at 30 parts per billion (ppb). 39 F.R. 42749 (Dec. 6, 1974).

6. In 1969, the action level was reduced to 20 ppb, which is the current action level for aflatoxin contamination in corn. Complaint ¶ 4; 39 F.R. 42749 (Dec. 6, 1974).

7. In January, 1978, FDA granted to the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina and Virginia an exemption from 21 C.F.R. § 110.99(d), which prohibits the blending of adulterated with less contaminated corn. Plaintiffs' Exhibit 2. FDA did not publish a notice of this action until April 4, 1978. 43 F.R. 14122-14123.

8. In November, 1978, FDA granted to the States of North Carolina, South Carolina and Virginia another exemption from its prohibition on blending adulterated with less contaminated corn. Plaintiffs' Exhibits 3 and 4. At the same time, FDA granted an exemption from its 20 ppb action level by permitting the interstate shipment of corn containing up to 100 ppb aflatoxin, for use as feed for mature, non-lactating livestock and mature poultry. *Id.*

9. FDA granted the exemptions referred to in Paragraph 8 by way of telegrams to the Agricultural Departments of those three states. *Id.* It did not publish a notice until January 23, 1981. 48 F.R. 7447.

10. FDA has never established a formal tolerance level for aflatoxin contamination in corn, under section 406 of the FDC Act. Complaint ¶ 13.

11. Plaintiff Community Nutrition Institute ("CNI") is a non-profit public interest organization established to promote the formation of a sound food policy that serves the health needs of consumers at the community level. Compaint ¶ 4. CNI has long been active in opposing the sale of foods containing unsafe additives and other ingredients, and in a letter to FDA dated October 6, 1980, specifically opposed the FDA policies now challenged in this case. Complaint ¶ 4; Plaintiffs' Exhibit 1.

12. CNI is supported, in part, by annual contributions in the form of subscriptions from approximately 6,000 persons. Compaint ¶ 4. CNI brings this action on behalf of its supporters and also its approximately 28 employees, most or all of whom consume corn and related corn products, and milk and meat from animals which consume corn as feed, including corn containing aflatoxin. *Id.*

13. Plaintiff Public Citizen is a non-profit, public interest organization supported by annual contributions from approximately 40,000 persons. Complaint ¶ 5. Its Health Research Group ("HRG") is engaged in research and advocacy to promote safe food and drugs, and it has long opposed the sale of aflatoxin-contaminated food products. Public Citizen brings this action on behalf of its contributors and its approximately 52 employees, most or all of whom consume corn and related corn products, and milk and meat from animals fed on corn, including corn containing aflatoxin. *Id.*

14. Plaintiffs Linda S. Bardot and Laura A. Rogers are individuals who regularly eat corn and foods containing corn meal, and also drink milk and eat poultry, beef and pork, which come from animals fed on corn, including corn containing aflatoxin. Complaint ¶¶ 6-7.

Respectfully submitted,

/s/

Diane B. Cohn
William B. Schultz
Alan B. Morrison

Public Citizen Litigation Group
2000 P Street, N.W.,
Suite 700
Washington, D.C. 20036
(202) 785-3704

Attorneys for Plaintiffs

March 10, 1982

EXHIBIT 2

Mr. Arthur Laramie
Louis Dreyfus Corporation
24 Richmond Hill Avenue
Stanford, Connecticut 06904

Dear Mr. Laramie:

This is in response to your letter of December 6, 1977, to Mr. Ceasar Roy, the director of the Division of Regulatory Guidance for FDA's Bureau of Foods, requesting that FDA permit 22,000 bushels of aflatoxin-contaminated corn located at your Pascagoula, Mississippi, grain elevator to be blended with uncontaminated corn and used for animal feed.

Corn which contains aflatoxin in excess of the established action level of 20 parts per billion (ppb) is an adulterated food under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a)(1). Use of an adulterated food as an ingredient in another food causes the finished food to be deemed to be adulterated, even if the finished product itself does not violate an established tolerance or action level. Tolerances and action levels for poisonous or deleterious substances such as aflatoxin apply only to unavoidable levels of contamination. Intentional blending of a violative article with an uncontaminated article is wholly avoidable and not authorized by such tolerances or action levels. Accordingly, the law does not permit you to blend adulterated corn with unadulterated corn as proposed in your letter.

Blending results in the redistribution rather than elimination of a contaminant. Since strict prohibition of blending helps eliminate from the food chain foods which contain contaminants at levels above the tolerance, consumer exposure to the contaminant is likely to be, on the average, at a level below the established tolerance. In

establishing tolerances, the degree of human exposure to the contaminant has been given consideration. If contaminated foods are permitted to enter the food chain by blending, the average exposure of the consumer will increase.

The observations of carcinogenic and other toxicologic effects of aflatoxin in animals and the positive correlations established between dietary aflatoxin and primary liver cancer in humans are of sufficient concern to warrant action to hold the human exposure to aflatoxins to the lowest practicable limit. The establishment of a tolerance is required to protect the public health and reduce human exposure to aflatoxins to be lowest practicable limit as determined by current technological capabilities to prevent or remove aflatoxin contamination of foods.

Since your letter asks about possibilities for use of the contaminated corn, we offer the following observations:

Export. Section 801(d)(1) of the FD&C Act permits export of an adulterated food if it:

(A) accords with the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

FDA would not object to exportation of aflatoxin-contaminated corn in compliance with the conditions established by section 801(d)(1) of the act.

Note that, subject to the conditions of section 801(d)(1)(A) through (D), you *are* permitted to blend corn intended for export to produce a composite lot which meets the specifications of the foreign purchaser and is in accord with the laws of the country to which it is intended for export. Although the blending would cause the food to

be adulterated, if not intended for export, section 801(d)(1) exempts a food intended for export from adulterated status, subject to conditions (A) through (D).

Before export of corn which is adulterated because of aflatoxin contamination, pursuant to section 801(d)(1), you should procure documents specifically establishing that the level of contamination is acceptable to the foreign purchaser and is not in conflict with the laws of the country to which the corn is intended for export, and the documents should be kept in your permanent files. FDA will not hesitate to institute regulatory action (including criminal prosecutions) for export of aflatoxin-adulterated corn in violation of the conditions of section 801(d)(1).

Sale to *distillers or corn processors.* You may sell the contaminated corn for use by distillers or food processors if the use to be made of the corn will result in no aflatoxin in the finished product or products. Any aflatoxin-contaminated by-product, such as mash from distillation, would have to be disposed of for uses other than food or feed.

Special considerations arising out of 1977 southeastern harvest aflatoxin problem. We recognize that farmers and elevator operators in the southeastern United States face an unusual and economically-devastating problem with respect to aflatoxin contamination of the 1977 corn harvest. It appears that over half of the 1977 corn crop in the southeastern United States (Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Virginia) may exceed the 20 ppb action level. (If contaminated corn is not introduced into interstate commerce, the local State law will govern use of the corn, assuming the corn is not used as an ingredient in food which is thereafter shipped in interstate commerce.)

Since it may be difficult for farmers in this area to find adequate supplies of corn for use in feeding animals if the law is enforced fully, the Commissioner has determined

that he will not recommend regulatory action for violation of the FD&C Act with respect to blending of such corn for use as animal feed if *all* of the following conditions are met:

(1) A technically feasible plan for blending must be provided, the plan to be approved by the FDA district office in Atlanta, Georgia, before blending operations commence. It must be demonstrated that the blending plan can reasonably be expected to result in a finished lot of corn containing less than 20 ppb of aflatoxin. the blending must be accomplished under Federal or State supervision, and the finished lot must be approved by Federal or State authorities before shipment in interstate commerce. It must be demonstrated to the satisfaction of the supervising Fed ral or State authority that the aflatoxin level of the blended lot is below 20 ppb.

(2) The aflatoxin-contaminated corn must not have been shipped in interstate commerce prior to FDA approval of the blending plan. (If FDA were to approve blending of corn after shipment in interstate commerce, there would be an unacceptable risk that some persons might ship contaminated corn in interstate commerce and blend only if the contaminated shipments were detected by Federal or State authorities. This condition should provide an incentive for farmers and elevator operators to treat corn for aflatoxin contamination *before* shipment in interstate commerce.)

(3) The blended lot must be offered for use only for animal feed for mature poultry, swine and beef animals other than milk-producing animals. (Aflatoxin is more likely to accumulate in the milk than in other tissues of animals consuming aflatoxin-contaminated corn and may harm young animals. The risk of undetected "pockets" of high aflatoxin

content corn within the blended lot is too great to authorize the use of blended corn for milk-producing or young animals.) Because aflatoxin is such a potent carcinogen, FDA will not under any circumstances authorize the blending for human consumption of corn exceeding the aflatoxin action level.

(4) This approval for limited blending applies only to corn harvested in the southeastern United States (Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Virginia) during the 1977 harvest. But for the widespread presence of unavoidable aflatoxin contamination in this region during this harvest, resulting in acute regional shortages of feed corn containing aflatoxin below the usual action level, FDA would not tolerate any blending of aflatoxin-contaminated corn.

Although it appears to us that this exception policy with respect to blending is not applicable to the 22,000 bushels of corn at your Pascagoula, Mississippi, grain elevator (because that corn appears to have been shipped in interstate commerce), the above discussion concerning blending may be helpful with respect to other aflatoxin-contaminated lots.

Sincerely yours,

/s/

Donald Kennedy
Commissioner of Food and Drugs

cc: HF-1(2)
HF-2
HFF-1
GCF-1
HFC-1
HFO-1
HFF-310
HFI-1
HFL-1
HFF-300
HFO-300
HFC-20
HFV-1
HFC-13
Atlanta R.O. (Kinslow)
New York R.O.

Prepared by SMcNamara/mz: 1/11/78
Approved by: T. Quinn: 1/19/78
H. Roberts: 1/19/78
R. Cooper: GCF-1: 1/19/78
Initialed by: J. R. Wessel HFC-13 1/20/78
J. P. Hile HFC-1 1/20/78
S. Gardner 1/23/78
D. Kennedy 1/23/78

f/t:jjs:1-31-78

EXHIBIT 3

TELEGRAPHIC MESSAGE **ISSUED: 10/9/80**

To: G. Bryan Patrick, Jr., Commissioner, South Carolina Department of Argiculture

From: Joseph P. Hile, Associate Commissioner for Regulatory Affairs, Food and Drug Administration

Info: Atlanta District, HFR-4100

This responds to your letter of September 19, 1980 in which you submitted a proposed plan for controlling the interstate shipment of corn which will be certified by your agency as containing less than 100 ppb aflatoxin, in response to my September 12, 1980 telegram. Data which you submitted with your letter, indicates that approximately 73 percent of the 1980 South Carolina corn crop contains aflatoxin in excess of our administrative guideline of 20 ppb. We agree that an emergency situation exists and that special limited exemptions for the shipment in interstate commerce of corn exceeding the 20 ppb action level are necessary to prevent substantial adverse economic impact on the South Carolina farmers and the food supply, and to minimize the possibility of contaminated corn being used for human food or being fed to dairy animals.

We believe your proposed plan provides for adequate control mechanisms over such interstate shipments. We understand that your proposal was intended to be exactly like that of North Carolina's submission but that certain transcription errors resulted in apparent discrepancies. There are additionally certain items in your plan which require clarification and modification.

Item 4

References to analytical procedures should be more specific by stating that each sample will be analyzed by 13 AOAC 26.050–26.051. Each sample will be analyzed in duplicate and the average of the duplicate analyses used as the acceptance or rejection level.

Items 3 and 5

It appears that the word "screen" in the first sentence of item 3 should be "stream".

We agree that for nonblended lots the sampling procedure outlined in item 3; i.e., 1-10 lb sample per lot, is adequate if collected from ten locations. A rejection limit of 80 ppb will afford sufficient assurance that a lot containing a true mean of 100 ppb or more aflatoxin will be rejected at least 95 percent of the time. However, we believe that blended lots should be sampled more thoroughly to assure there was uniform mixing of the lot. For blended lots, two 10 pound samples should be drawn randomly from each lot following the procedures detailed in Item 3. Each 10 pound sample should be analyzed in duplicate. The average of the duplicate analyses of each two ten pound sample must not differ by more than 50 ppb (Two times the square root of two, times the standard error associated with the analytical and sampling errors), and the average of the four analyses must not exceed 80 ppb. If blending fails, reblending will be permitted.

Items 6 and 7

We agree with your proposed labeling except that the term "animals" should be replaced with the term "livestock." Because of the possible difficulty of maintaining an appropriate label on the "containers" of corn to be shipped, the bill of lading and other related documents (e.g., invoices) should also bear the aflatoxin content of

the lot and the phrase "to be fed only to nonlactating mature livestock or poultry." In Item 7, line 3, you state that records of "date sent" will be kept. You should also indicate on records the date the lot is sampled and also keep appropriate records documenting the integrity of the shipment to the receiving state (i.e., railcar seals, numbers of such seals, etc.). The bill of lading should also bear the seal numbers or other identification to relate it to the lot.

Item 8

We recognize that specific agreements with States receiving shipments may vary; however, we believe that all agreements should require written documentation from the ultimate user, stating that he agrees to feed the corn only to nonlactating mature livestock or poultry. The agreement should also identify the agency in the receiving state that will be responsible for monitoring the shipment to destination. Please submit copies of these agreements to the FDA Atlanta Regional office, attention Mr. Maurice Kinslow as soon as they are developed. If we have questions or concerns over their adequacy, the region will contact you immediately. Procedures for notification for individual shipments should be agreed upon by you and Atlanta region. These procedures must provide for special designation of blended lots.

Item 9

As stated in the meeting with Mr. Quinn on September 16, 1980, authorization for blending must be on a firm-by-firm basis. We request that you submit copies of each approved plan for blending to the FDA Atlanta Regional office. This will simplify our working with you on this program.

Item 11

It appears that the word "notification" should be "certification".

Page 3, paragraph 2

We cannot agree to this. Any interstate shipment of corn from South Carolina exceeding the 20 ppb action level may only be shipped under the auspices of this plan to which we have agreed. Any shipments made independent of this plan would, if found to exceed the 20 ppb action level, be considered adulterated and subject to condemnation. Thus, it is imperative that all potential corn shippers in your state be notified of this plan.

We ask that you revise your plan as outlined in this letter; also that you distribute your plan to your counterpart agencies in other states as well as to the other affected parties as you describe in Item 14.

FDA will periodically audit shipments made under this program to assist the states in assuring proper implementation of this program. We will do our utmost to expedite our response to any requests you make relative to this problem.

/s/

Joseph P. Hile

cc: HFC-1;HFC-2;HFC-6;HFC-20
HFR-41
HFR-4100
HFO-500
HFO-20
HFO-30
HFF-1
HFF-300
HFF-310
HFF-314(Phillips, r/f)
HFF-454(Stoloff)
HFV-200
HFV-230
HFL-1
HFF-300 r/f
R/D: F A Phillips: jn:10/2/80
Init: T M Quinn: 10/2/80
Concurred: R Moats: 10/3/80
G White: 10/3/80
E Ballitch: 10/3/80
C E. Coker: 10/6/80
RT:wcm: 10/7/80
Concur: E Ballitch: HFV-230: 10/7/80
S Terman: GCF-1: 10/7/80
A Celeste: HFO-20: 10/7/80
T Quinn: HFF-300: 10/8/80-by phone
FT:wcm: 10/8/80

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COI UMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEFENDANT.

DEFENDANT'S RESPONSE TO PLAINTIFFS' STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE ISSUE

Pursuant to Rule 1-9(h) of the Rules of this Court, defendant submits its statement of genuine issues and its response to plaintiffs' statement of material facts as to which there is no genuine issue:

1. Paragraph 1 is admitted.

2. Paragraph 2 is admitted except to the extent that plaintiffs suggest that all aflatoxins are liver carcinogens in all test animals. The Federal Register Notice plaintiffs cite states that certain of the aflatoxins are liver carcinogens in some species of test animals.

3. Paragraph 3 is admitted except to the extent that plaintiffs suggest that the studies discussed in the Federal Register Notice plaintiffs cite do anything more than indicate a general correlation between the incidence of primary liver cancer in humans and exposure to aflatoxins in several population groups in Southeast Asia and Africa, where (a) the level of aflatoxin contamination of corn and peanuts averaged around 100 parts per billion (ppb) in 95 and 80 percent, respectively, of the samples, (b) 20 percent

of the food staples contained an average of 300 ppb aflatoxin, or (c) there was a high incidence (7 percent) of low levels (3-4 ppb) of aflatoxin in family meals.

4-6. Paragraphs 4-6 are admitted.

7. Paragraph 7 is admitted except to deny that the exemption to which plaintiffs refer was an exemption from 21 C.F.R. § 110.99(d). Section 110.99(d) has nothing to do with corn for animal feed, action levels, or blending corn—whether for consumption by man or any other animal—containing aflatoxins in excess of FDA's 20 ppb action level with corn containing less than 20 ppb aflatoxins. Statement of Taylor M. Quinn, ¶ 12.

8. Paragraph 8 is admitted except to deny that the exemption to which plaintiffs refer was granted in 1978. The exemption was granted in 1980. 48 Fed. Reg. 7,447 (January 23, 1981).

9-10. Paragraphs 9 and 10 are admitted.

11. Paragraph 11 is admitted except to deny that plaintiff Community Nutrition Institute opposed, by letter to FDA dated October 6, 1980, any of the FDA actions challeged in this case except the exemptions granted in 1980. Indeed, none of the plaintiffs has ever brought to FDA's attention, except in the context of this case, any of the actions plaintiffs challenge here other than those exemptions. Statement of Linda M. Quinones, ¶ 's 4-9.

12-14. Paragraphs 12-14 are admitted.

Respectfully submitted,

/s/
STANLEY R. HARRIS
United States Attorney

/s/
ROYCE C. LAMBERTH
Assistant United States Attorney

/s/
PATRICIA J. KENNEY
Assistant United States Attorney

OF COUNSEL:

/s/
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Chief Counsel

STEPHEN D. TERMAN
Associate Chief Counsel for Enforcement

MICHAEL M. LANDA
Associate Chief Counsel for Enforcement

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

/s/
BEVERLY SHERMAN NASH
Attorney
Consumer Affairs Section
Antitrust Division
Department of Justice

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR. COMMISSIONER, FOOD AND DRUG ADMINSTRATION, DEFENDANT.

DEFENDANT'S STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE DISPUTE

Pursuant to Rule 1-9(h) of the Rules of this Court, defendant submits the following statement of material facts as to which there is no genuine dispute.

1. Plaintiff Community Nutrition Institute ("CNI") is a non-profit organization. CNI long has been active in opposing the sale of foods containing unsafe food additives and ingredients. (Complaint ¶ 4.)

2. Plaintiff Public Citizen is a non-profit organization. Its Health Research Group ("HRG") is engaged in research and advocacy to promote safe and effective food and drugs. (Complaint, ¶ 5.)

3. Plaintiff Linda S. Bardot is an employee of CNI. She and her family are consumers who eat poultry, beef, and pork, all of which may be derived from animals raised in part on corn. (Complaint, ¶ 6.)

4. Plaintiff Laura A. Rogers is a consumer who eats poultry, beef, and pork, all of which may be derived from animals raised in part on corn. (Complaint, ¶ 7.)

5. Named defendant Jere G. Goyan was the Commissioner of Food and Drugs at the time of the acts alleged in the Complaint. As Commissioner, and pursuant to 21 C.F.R. § 5.1, he acted as the designate of the Secretary of

Health and Human Services in enforcing provisions of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.* He was succeeded in office by Arthur Hull Hayes, Jr. on April 13, 1981.

6. The aflatoxins are a group of chemically related substances produced as natural by-products of the growth of certain common molds. The toxicity of aflatoxins, the manner in which they can contaminate foods, and the unavoidability of the contamination are described in "Aflatoxin-Contaminated Corn; Limited Exemptions from Prohibition of Interstate Shipment and Blending: Assessments of Safety and Impact in the National Food Supply," Food and Drug Administration, December (1980), pp. 1, 2, 7, 8 (the "Safety Assessment"), attached as Exhibit 7 to the Statement of Taylor M. Quinn, and incorporated by reference.

7. In the United States, the levels of aflatoxin in corn vary from region to region and within regions, from year to year. Statement of Leonard Stoloff, ¶ 's 5-11.

8. Residues of aflatoxin may appear in the edible tissues, eggs, and milk of animals fed aflatoxin-contaminated feeds, including corn. There is, however, no known method for removing aflatoxin residues from meat, eggs, milk, or dairy products after contamination has occurred. Safety Assessment, pp. 7-8.

9. FDA enforces 21 U.S.C. § 342(a)(1) against aflatoxin in corn and other susceptible commodities by means of an internal regulatory standard, called an "action level," which represents the agency's prosecutorial judgment as to the level of contamination at which the FDA is prepared to recommend to the United States Department of Justice regulatory action under the Act—seizure (21 U.S.C. § 334), injunction (21 U.S.C. § 332), or prosecution (21 U.S.C. §§ 331, 333). Since 1969, the agency's action level for aflatoxin in human food and animal feed has been 20 parts per billion (ppb). Statement of Taylor M. Quinn, ¶ 4.

10. The basis for the action level is described in the Quinn Statement, ¶'s 5,6,7, and incorporated by reference. An "action level" is not the same as a "defect action level." Defect action levels apply solely to natural or unavoidable non-hazardous defects in food—"esthetic" adulterants such as microscopic amounts of tomato mold and rot in processed tomato products—and have nothing to do with action levels, which apply solely to poisonous or deleterious substances in food. *Id.*, ¶ 12.

11. Corn containing up to 100 ppb aflatoxin does not present a reasonable possiblility of injury either to the health of mature, non-lactating livestock (beef cattle or swine) or mature poultry or to the health of humans who consume meat or eggs derived from these animals. Stoloff Statement, ¶ 4; Quinn Statement, ¶'s 6-7; Safety Assessment, p. 5. Indeed, meat from beef cattle, poultry, swine, and eggs from laying hens fed corn containing up to 100 ppb aflatoxin contain less than 0.1 ppb aflatoxin, the lowest level that can be consistently identified and measured in tissues by available analytical methods. Safety Assessment, pp. 3-6.

12. In 1978, under 21 C.F.R. § 509.8, FDA established a limited exemption to its prohibition against blending corn containing aflatoxin above its 20 ppb action level with less contaminated corn to achieve a level below 20 ppb, and then shipping the corn in interstate commerce. Notice of the exemption was published in the Federal Register of April 4, 1978 (43 Fed. Reg. 14,122), and the information supporting FDA's determinations was referred to in the notice and placed in the administrative file. The exemption applied only to corn harvested in 1977 in the southeast United States and required, among other things, that FDA approve a plan for blending before blending operations began and before the corn had been shipped in interstate commerce. *Id.* at 14,123.

The exemption established in the 1978 notice expired on January 1, 1979. *Id.* No firm or individual ever sought to take advantage of the exemption by requesting that FDA approve a plan for blending. Quinn Statement, ¶ 9(a). No comments on the 1978 notice were received from any of the plaintiffs. Statement of Linda M. Quinones, ¶ 2.

13. In September and October 1980, the States of North Carolina and South Carolina and the Commonwealth of Virginia requested limited exemptions from FDA's prohibition of interstate shipment and blending of corn containing aflatoxin above its 20 ppb action level.

In November 1980, under 21 C.F.R. § 509.8, FDA granted the states' requests for exemptions. The exemptions, which expired on January 1, 1982, were announced by a notice published in the Federal Register of January 23, 1981. 46 Fed. Reg. 7,447-7,449. The information on the basis of which FDA granted the exemptions includes the Safety Assessment and 18 documents, primarily published studies about aflatoxin, referred to therein. Quinn Statement, ¶ 9(b).

The state exemptions applied only to the 1980 corn crop harvested in North Carolina, South Carolina, and Virginia and provided that FDA would not recommend regulatory action against such corn and which contained between 20 ppb and 100 ppb aflatoxin or which was blended to achieve a level of no more than 100 ppb aflatoxin if, among other things, the corn was used only for feeding mature, nonlactating livestock and mature poultry. 46 Fed. Reg. at 7,448. The notice stated that in all other cases, FDA's prohibition of interstate shipment and blending of corn containing aflatoxin in excess of the agency's 20 ppb level "will be applied." *Id.* at 7,449; Quinn Statement, 9(b).

The state exemptions did not grant permission to ship a single lot of aflatoxin contamined corn; rather, they specified a procedure under which lots of aflatoxin-contaminated corn could be shipped in interstate com-

merce once specific terms and conditions were met. Thus, a decision by FDA not to recommend regulatory action against corn subject to the exemptions was contingent upon state and industry compliance with detailed control plans designed to ensure that (1) corn containing between 20 ppb and 100 ppb aflatoxin was not diverted for uses other than as feed for the above animals and (2) blending of corn achieved a level of no more than 100 ppb aflatoxin.

Although the exemptions required that any firm or individual wishing to take advantage of them apply to the states involved for permission to ship or blend and then ship in interstate commerce corn subject to the exemptions, the exemptions also required that FDA be notified before any shipment was made and when the shipment was received. FDA, therefore, closely monitored the exemptions, and enforced compliance with them. *Id.*, ¶ 's 9(b), 11.

14. By letter to defendant dated October 6, 1980, CNI urged FDA to deny North Carolina's and South Carolina's requests for exemptions, as well as any similar request the agency might receive. By letter to CNI dated November 28, 1980, FDA responded to each of CNI's objections, and rejected the Institute's request that the agency not grant an exemption either from the 20 ppb action level or the policy prohibiting blending. *Id.*, ¶ 10.

15. The state exemptions expired on January 1, 1982. 46 Fed. Reg. 7,447. Two shipments containing a total of seven railcars of aflatoxin-contaminated corn were made under the exemptions, one on April 15, 1981, and the other on April 21, 1981. Quinn Statement, ¶ 9(b).

16. No petition pursuant to 21 C.F.R. § 10.25, 21 C.F.R. § 109.5, or 21 C.F.R. § 509.5 for the establishment of a formal tolerance for aflatoxin in corn has been received from any of the plaintiffs. Quinones Statement, ¶ 4.

17. No comments were received from CNI, Linda S. Bardot or Laura A. Rodgers concerning FDA's Notice of proposed rulemaking for "Poisonous or Deleterious Substances in Food," 39 Fed. Reg. 42,743 (December 6, 1974) (Docket No. 77N-0166). Quinones Statement, ¶ 9.

18. FDA received a letter dated February 24, 1975, from Public Citizen, through HRG, commenting on FDA's "Proposed Tolerance; Aflatoxin in Shelled Peanuts and Peanut Products Used as Human Food," Federal Register Notice of December 6, 1974 (39 Fed. Reg. 42,748) (Docket No. 78N-0048). Quinones Statement, ¶ 10.

Respectfully submitted,

STANLEY R. HARRIS
United States Attorney

OF COUNSEL:

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Antitrust Division
Department of Justice

UNITED STATES DISTRICT COURT
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COMMUNITY NUTRITION INSTITUTE ET AL., PLAINTIFFS,

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ARTHUR HULL HAYES, JR. COMMISSIONER, FOOD AND DRUG ADMINSTRATION, DEFENDANT.

STATEMENT OF TAYLOR M. QUINN

1. I, Taylor M. Quinn, am Associate Director for Compliance, Bureau of Foods, United States Food and Drug Administration ("FDA"). In this capacity I am responsible for FDA's enforcement of the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, pertaining to food. I have been involved in the enforcement of the Act for about 30 years, including 11 years as an Inspector, 9 years as a Consumer Safety Officer, 6 years as Director of the Division of Regulatory Guidance, Bureau of Foods, and nearly 4 years in my present position.

2. My duties require that I be, and I am, generally familiar with problems related to aflatoxin-contamination of food, including how the contamination occurs, what can and cannot be done to prevent the contamination, and the nature of the risks to health presented by the contamination. My knowledge in this area is obtained through a variety of methods, including reading of published and unpublished reports, discussions with plant pathologists, toxicologists, public health officials, and agency personnel, and meetings with members of the food industry.

3. During the course of my official duties, I participated in the formulation of FDA's regulatory policy with respect to aflatoxin-contaminated foods, including corn, and FDA's regulations on poisonous and deleterious substances in human food and animal feed, 21 C.F.R. §§ 109 and 509.

4. Under the FD&C Act, a food is deemed to be adulterated if, among other things, it bears or contains an added poisonous or added deleterious substance which may render the food injurious to health. 21 U.S.C. § 342(a)(1). Thus, a food is adulterated within the meaning of section 342(a)(1) if it presents a reasonable possibility of injury to humans or animals. FDA guides enforcement under 21 U.S.C. § 342(a)(1) against aflatoxin in corn and other susceptible commodities by means of internal regulatory standard, called an "action level," which represents the agency's prosecutorial judgment as to the level of contamination at which FDA is prepared to recommend to the United States Department of Justice regulatory action under the Act—seizure (21 U.S.C. § 334), injunction (21 U.S.C. § 332), or prosecution (21 U.S.C. §§ 331, 333). Since 1969, the agency's action level for aflatoxin in food and feed has been 20 parts per billion (ppb).

5. The action level is based on four considerations:

(a) Direct consumption by humans of agricultural commodities containing more than 20 ppb aflatoxin may be injurious to their health;

(b) Milk from dairy cattle fed corn or other commodities containing more than 20 ppb aflatoxin may be injurious to the health of infants because residues of aflatoxin may appear in the milk of such cattle. Milk, of course, occupies a unique position in the diet of infants.

(c) Direct consumption by young animals of feed containing more than 20 ppb aflatoxin may be injurious to their health; and

(d) Although consumption by most food producing animals would raise no public health concern, FDA does not have the enforcement resources to ensure that agricultural commodities containing more than 20 ppb aflatoxin are not used as food for humans, dairy cattle, or young animals.

6. FDA has not determined that animal feed, including corn, containing more than 20 ppb aflatoxin, may be injurious to all species of food producing animals or to humans who consume edible products from such animals. Indeed, to FDA's knowledge there is no qualified expert who will testify that corn containing between 20 ppb and 100 ppb aflatoxin presents a reasonable possibility of injury to mature, nonlactating livestock (beef cattle or swine) or mature poultry, or to humans who consume meat or eggs from those animals. Nonetheless, to ensure that no corn containing more than 20 ppb aflatoxin is consumed by humans, dairy cattle, or young animals, FDA's action level calls for regulatory action against all corn containing more than 20 ppb aflatoxin.

7. It has not been proved that the meat or eggs from mature, nonlactating livestock or mature poultry fed corn containing between 20 ppb and 100 ppb aflatoxin are safe—i.e., without any risk—for human consumption. As discussed in paragraph 6, however, FDA cannot show that such corn presents a reasonable possibility of injury either to those animals or to humans who consume edible products from then, and therefore lacks the evidence to support a charge of food adulteration under 21 U.S.C. § 342(a)(1). Thus, agency recommendations for regulatory action against corn containing between 20 ppb and 100 ppb aflatoxin often are made because at the time of the incipient seizure or injunction, FDA does not know the destination of the corn and will not risk the possibility that the corn ultimately will be consumed by humans, dairy cattle, or young animals instead of mature beef cattle, poultry, or swine.

8. Corn containing above 20 ppb aflatoxin and which has moved in interstate commerce, though above the agency's action level, is not automatically the subject of a recommendation for enforcement litigation. FDA regulations authorize the FDA to exempt from a recommendation for regulatory action any food containing a poisonous and deleterious substance if the agency determines that (1) based on all available evidence, the food is "safe" for consumption—i.e., involves no "significant health hazard," 39 Fed. Reg. 42743, 42746 (December 6, 1974)—and (2) destruction or diversion of the food would result in a substantial adverse impact on the national food supply. 21 C.F.R. §§ 109.8 (human food), 509.8 (animal feed). The regulations require publication in the Federal Register of FDA's determinations, an invitation to comment on them, and inclusion in the administrative file of the information supporting them.

9. FDA has granted exemptions under 21 CFR 509.8 on two occasions.

(a) In 1978, FDA established a limited exemption to its prohibition against blending corn containing aflatoxin above its 20 ppb action level with less contaminated corn to achieve a level below 20 ppb and then shipping the corn in interstate commerce. Notice of the exemption was published in the Federal Register of April 4, 1978 (43 Fed. Reg. 14122), and the information supporting FDA's determinations was referred to in the notice and placed in the administrative file. The exemption applied only to corn harvested in 1977 in the southeast United States and required, among other things, that FDA approve a plan for blending before blending operations began and before the corn had been shipped in interstate commerce. *Id.* at 14123.

The exemption established in the 1978 notice expired on January 1, 1979. *Id.* No firm or individual ever sought to take advantage of the exemption by requesting that FDA approve a plan for blending.

(b) In September and October 1980, the States of North Carolina and South Carolina and the Commonwealth of Virginia requested limited exemptions from FDA's prohibition of interstate shipment and blending of corn containing aflatoxin above its 20 ppb action level. These requests are attached hereto as Exhibits 1-3.

In November 1980, pursuant to and in accordance with 21 C.F.R. § 509.8, FDA granted the States' requests for exemptions. FDA's correspondence with the States is attached hereto as Exhibits 4-6. The exemptions, which expired on January 1, 1982, were announced by a notice published in the Federal Register of January 23, 1981. 46 Fed. Reg. 7447-7449. Only two shipments totalling seven railroad cars of aflatoxin contaminated corn were made under the exemptions, one on April 15, 1981, and the other on April 21, 1981, from South Carolina to Florida. The information on the basis of which FDA granted the exemptions includes "Aflatoxin-Contaminated Corn; Limited Exemptions from Prohibition and Interstate Shipment and Blending: Assessments of Safety and Impact on the National Food Supply," Food and Drug Administration, December 1980, and eighteen documents, primarily published studies about aflatoxin, referred to therein. The Assessment is attached hereto as Exhibit 7; the supporting documents are attched as Exhibits 1-18 to the Statement of Linda M. Quinones, Director, Dockets Management Branch, United States Food and Drug Administration filed with the Court.

The state exemptions applied only to the 1980 corn crop harvested in North Carolina, South Carolina, and Virginia and provide that FDA would not recommend regulatory action against such corn and which contained between 20 ppb and 100 ppb aflatoxin or which had been blended to achieve a level of no more than 100 ppb aflatoxin if, among other things, the corn was used only for feeding mature, nonlactating livestock and mature poultry.

46 Fed. Reg. at 7448. The notice stated that in all other cases, FDA's prohibition of interstate shipment and blending of corn containing aflatoxin in excess of the agency's 20 ppb action level "will be applied." *Id.* at 7449. Thus, the action level remains in effect and will be applied whenever (as is always true) the facts and circumstances of a particular shipment warrant a recommendation for regulatory action. Those facts and circumstances include the quantity of contaminated food or feed, the level of contamination, and the ultimate consumer (humans or animals, species, age.).

The state exemptions did not grant permission to ship a single lot of aflatoxin-contaminated corn; rather, they specified a procedure under which certain lots of aflatoxin-contaminated corn could be shipped in interstate commerce once specific terms and conditions were met. Thus, a decision by FDA to not recommend regulatory action against corn subject to the exemptions was contingent upon state and industry compliance with detailed control plans designed to ensure that (1) corn containing between 20 ppb and 100 ppb aflatoxin is not diverted for uses other than as feed for the above animals and (2) blending of corn achieves a level of no more than 100 ppb aflatoxin. The control plans were in large part developed by each of the three states, and were included as part of their exemption requests submitted to FDA.

Although the exemptions required that any firm or individual wishing to take advantage of them to apply to the states involved for permission to ship or blend and then ship in interstate commerce corn subject to the exemptions, the exemptions also required that FDA be notified before any shipment was made and when any shipment was received. FDA, therefore, closely monitored the exemptions.

The States of South Carolina and Georgia have made requests to FDA that exemptions be granted for corn harvested in their states in 1981. FDA has made no formal reply.

10. By letter to defendant dated October 6, 1980 plaintiff Community Nutrition Institute (CNI) urged FDA to deny North Carolina's and South Carolina's requests for exemptions, as well as any similar request the agency might receive. A copy of CNI's letter is attached hereto as Exhibit 8. A copy of FDA's response is attached hereto as Exhibit 9.

11. FDA will enforce compliance with the exemptions by revoking its commitment to not recommend regulatory action if FDA, through its monitoring or any other activities, finds that a state is not complying with the terms and conditions of the exemptions.

12. Plaintiffs allege that 21 C.F.R. § 110.99(d) prohibits blending food containing a poisonous and deleterious substance, for example, aflatoxin-contaminated corn, with another lot of food (Complaint, ¶ 17). Plaintiffs are wrong. Section 110.99(d) applies solely to unavoidable, non-hazardous defects in human food, for example, microscopic amounts of tomato mold and rot in processed tomato products. The phrase "defect action level" in 21 C.F.R. § 110.99(d) pertains solely to "esthetic" or "cosmetic" adulterants in food. "Defect action levels" have nothing to do with poisonous or deleterious substances in food, for example, aflatoxin in corn, and should not be confused with "action levels," described in paragraph 4.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing statement is true and correct.

Excuted on April ____, 1982.

TAYLOR M. QUINN
Associate Director for Compliance
Bureau of Foods
United States Food and Drug
Administration
Washington, D.C.

EXHIBIT 4

TELEGRAPHIC MESSAGE **CA 80-3110**

To: James A. Graham, Commissioner, Department of Agriculture, State of North Carolina

From: Associate Commissioner for Regulatory Affairs, Food and Drug Administration

This is to advise you that we have completed our review of the "North Carolina plan for control of interstate shipments of corn bearing or containing not more than 100 parts per billion aflatoxin," as revised in accordance with comments contained in our NRSTEN TWX of October 9, 1980. This revised plan adequately addresses previous comments and may be implemented immediately.

If any problems are encountered in implementing the plan Mr. Taylor M. Quinn (202-245-1243) or our Atlanta regional office should be advised immediately. Similarly, if evidence comes to our attention that the plan is not working in any particular way we will advise your office immediately to resolve the problems.

EXHIBIT 5

TELEGRAPHIC MESSAGE **CA 80-3110**

To: G. Bryan Patrick, Jr., Commissioner, Department of Agriculture, State of South Carolina

From: Associate Commissioner for Regulatory Affairs, Food and Drug Administration

This is to advise you that we have completed our review of the "South Carolina plan for control of interstate shipments of corn bearing or containing not more than 100 parts per billion aflatoxin," as revised in accordance with comments contained in our NRSTEN TWX of October 9, 1980. This revised plan adequately addresses previous comments and may be implemented immediately.

If any problems are encountered in implementing the plan Mr. Taylor M. Quinn (202-245-1243) or our Atlanta regional office should be advised immediately. Similarly, if evidence comes to our attention that the plan is not working in any particular way we will advise your office immediately to resolve the problems.

EXHIBIT 6

TELEGRAPHIC MESSAGE **CA 80-3110**

To: S. Mason Carbaugh, Commissioner, Virginia Department of Agriculture and Consumer Services

From: Associate Commissioner for Regulatory Affairs, Food and Drug Administration

This is to advise you that we have completed our review of the "Virginia plan for control of interstate shipments of corn bearing or containing not more than 100 parts per billion aflatoxin," as revised in accordance with comments contained in our NRSTEN TWX of October 9, 1980. This revised plan adequately addresses previous comments and may be implemented immediately.

If any problems are encountered in implementing the plan Mr. Taylor M. Quinn (202-245-1243) or our Philadelphia regional office should be advised immediately. Similarly, if evidence comes to our attention that the plan is not working in any particular way we will advise your office immediately to resolve the problems.

EXHIBIT 7
CA 80-3110
AFLATOXIN-CONTAMINATED CORN
LIMITED EXEMPTIONS FROM PROHIBITION
OF INTERSTATE SHIPMENT AND BLENDING

ASSESSMENTS OF SAFETY

AND

IMPACT ON THE NATIONAL FOOD SUPPLY

FOOD AND DRUG ADMINISTRATION
DECEMBER 1980

BACKGROUND

The Food and Drug Administration (FDA) has an established action level of 20 parts per billion (ppb) for aflatoxin contamination of corn for human or animal consumption (FDA Administrative Guidelines Manual, 7420.01 (5/16/79)).

FDA's regulations on Unavoidable Contaminants in Animal Food-Packaging Material, 21 CFR 509.8, provides for exemptions from established action levels based on all available evidence that the food is safe for consumption (i.e., no significant health hazard is involved) and that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

In order to determine whether to grant limited exemptions to its existing policy prohibiting the interstate shipment and blending of corn containing aflatoxin above the action level with less contaminated corn, FDA has considered the safety of such action and its impact on the national food supply. These exemptions provide for interstate shipment of corn containing aflatoxins up to a level of 100 ppb and the blending of aflatoxin contaminated corn to achieve aflatoxin levels of 100 ppb or

less. Under the exemptions, such corn is restricted to use as feed or feed ingredients for mature nonlactating livestock and mature poultry. The exemptions were requested by the states of North Carolina and South Carolina and the Commonwealth of Virginia.

Aflatoxins are a group of highly toxic chemicals produced by molds that can sometimes contaminate susceptible foods such as peanuts and corn. One of the aflatoxins, known as B_1, is a potent liver carcinogen in some species of experimental animals. Information bearing on the assessment of possible hazard to humans from aflatoxin ingestion is presented (reference 1).

FDA imposed regulatory guidelines to limit the aflatoxin content of peanuts, corn, their manufactured products, and other susceptible commodities. A limit of 30 ppb total aflatoxins (four toxins, called B_1, B_2, G_1 and G_2) based on analytical capability was set in 1965. In 1969, based on improvements in analytical capability, this guideline was reduced to 20 ppb, where it stands today.

SUMMARY OF EVIDENCE OF SAFETY

Aflatoxin contamination of feed corn is of concern because it can affect animal health, and because such animals provide edible tissues (meat, milk, and eggs) for human consumption. When feed containing aflatoxins is ingested by dairy cattle, beef cattle, poultry, or swine, the largest portion of the aflatoxins is eliminated in excreta, but residues of aflatoxins may be found in the edible tissues of those animals under certain circumstances.

Both unmetabolized aflatoxin B_1 and the chemically related but less potent carcinogen, aflatoxin M_1 (a compound produced from B_1 by normal biological processes of the ingesting animals, i.e., M_1 is a metabolite of B_1), can sometimes be detected as residues in edible tissues. Almost all studies related to aflatoxins fed to livestock are based on examination of edible tissues for B_1 and M_1.

Other aflatoxins, e.g., B_2, G_1, and G_2, usually occur at levels substantially lower than B_1; consequently, they have been found in edible tissue only after feeding of aflatoxins at levels so high that animal health is affected. The quantitative relationships between feed levels of aflatoxins and edible tissue levels of B_1 and M_1 is considered below.

- An analysis has been made of currently available information regarding aflatoxin. It has been determined that 0.1 ppb aflatoxin is the lowest level that can be consisently identified and measured in tissues by available analytical methods (references 2, 3, and 4).

Information on the quantitative relationships between feed levels of aflatoxins and levels of aflatoxin residues occurring in edible tissues has been assembled and assessed (references 5, 6, and 7). The studies which produced this information varied considerably in the dosing schedule of the animals, the breed of animals, the mode of administration of the aflatoxins, the levels of aflatoxins administered, the experimental period, and the source of aflatoxin used (e.g., purified B_1 vs. mold-contaminated feed).

A tabular review (reference 9) of information pertinent to this assessment from published reports through 1977 is presented. This includes information on the specific tissues in which aflatoxin residues occur. For each major food-producing animal, the single tissue and type of aflatoxin which together provide the lowest feed to tissue ratio were selected. Where both B_1 and M_1 occurred as residues, B_1 was chosen as the aflatoxin of interest because of its predominance and its more potent carcinogenic properties compared to M_1. By the above criteria the aflatoxin and edible tissues that provide the most sensitive indicator of aflatoxin contamination are: aflatoxin B_1 in the livers of beef cattle, swine and broilers, aflatoxin B_1 in eggs, and aflatoxin M_1 in the milk of dairy cattle.

Based on the foregoing information, the most likely ratios of the level of aflatoxin B_1 in feed to the level of aflatoxin B_1 or M_1 in various edible tissues have been estimated. These are presented in Table I.

Table I

Animal	Edible Tissue	Aflatoxin in Tissue	Estimated Aflatoxin Feed/Tissue Ratio
Beef cattle	Liver	B_1	14,000
Dairy cattle	Milk	M_1	300
Swine	Liver	B_1	800
Layers	Eggs	B_1	2,200
Broilers	Liver	B_1	1,200

The aflatoxin B_1 levels in feed which might result in the minimum measurable residue of aflatoxin in tissue (0.1 ppb) are about 1/10th of the values in the last column of Table I, e.g. 1400 ppb aflatoxin in the feed of beef cattle would result in a estimated 0.1 ppb aflatoxin in the edible tissue (i.e. liver) of the cattle.

On the basis of the above estimates, FDA concluded that an exemption could be made to the existing action level of 20 ppb aflatoxins in corn intended for use as an ingredient in the feed rations of certain food-producing animals. Specifically, the agency concluded that corn containing up to 100 ppb aflatoxins could be fed to mature cattle (except lactating dairy cattle), swine and poultry without posing a significant health hazard or even a significant increase in risk to consumers of food from these animals. This conclusion is based on the following considerations. The existing level of 20 ppb, which is applicable to individual feed ingredients, as well as complete feed rations, ensures that aflatoxins will not occur at levels

higher than 0.1 ppb in edible tissues of animals. Levels of 0.1 ppb or less aflatoxin in food derived from animals represents an insignificant fraction of the total human dietary exposure to aflatoxins.

According to Table I, and since corn does not usually comprise an animal's total ration, aflatoxin B_1 levels up to 100 ppb in corn fed to mature nonlactating livestock and mature poultry also should not cause a level of aflatoxin in edible tissues above 0.1 ppb.

The 800:1 feed:tissue ratio for swine in Table I does indicate that residues might be detected in swine liver when aflatoxin levels exceed 80 ppb in the animal's total ration. However, because corn is usually fed with other ingredients, the aflatoxin levels in the total swine ration will be lower than in the corn alone. Accordingly, aflatoxin residues in the liver from the total ration are not expected to exceed the 0.1 ppb level of detection. A practical test of experimental determinations regarding aflatoxin transfer from feed to tissue residues was conducted by the U.S. Department of Agriculture's Food Safety and Quality Service (FSOS) for a year starting October 1977, when again much of the Southeastern corn crop was contaminated with aflatoxins at levels frequently exceeding 100 ppb. See "Notice; Aflatoxin Contaminated Corn, Limited Exemption from Blending Prohibition," 43 *Federal Register*, 14122, 14123 (April 4, 1978). Random samples of hog, cattle, and poultry livers, as well as liquid eggs, in the Southeast were analyzed for aflatoxins by a method capable of detecting 0.05 ppb. No aflatoxin was detected in any sample (reference 10). An FDA survey of shell eggs on the Southeast retail market in November 1977 also failed to detect aflatoxin (reference 11). Therefore, allowing corn containing up to 100 ppb total aflatoxins to be used for the animals listed above would not pose a significant health hazard or even significantly increase the risk to the public health from dietary exposures to aflatoxin.

The 20 ppb action level for dairy animal feed and feed ingredients also prevents detectable residues from occurring in milk. However, as can be seen in Table I, aflatoxin contamination levels somewhat above the 20 ppb action level can cause detectable residues of M_1 in milk. Because of the unique position of milk in the infant diet and because the very young might be more susceptible to the effects of aflatoxins (reference 12), corn containing aflatoxins at levels above 20 ppb is not permitted in the feed of lactating dairy animals under the exemptions.

The safety of the contaminated feed for ingestion by animals must also be considered. Available information on the affects of aflatoxins on the health of various food-producing animals has been reviewed (references 7, 8, 13, and 14). Although levels of dietary aflatoxins which produce no adverse affects in livestock cannot be sharply defined from the available information, it is possible to make judgments about the probability of adverse effects.

The 100 ppb level for total aflatoxins is below any aflatoxin B_1 level that has caused adverse effects to mature livestock and poultry. However, the susceptibility of the very young to aflatoxicosis applies not just to humans, but to all animals. Therefore, no exemption for starter ration ingredients (i.e., feed for young animals) is being made.

AFLATOXIN PREVENTION AND CONTROL

Aflatoxin contamination of meat, milk, and eggs can be controlled by limiting the level of aflatoxin contamination of feed. There is no known method for removing aflatoxin residues from meat, eggs, or milk, or from products derived from milk, after contamination has occurred. Aflatoxin contamination of feeds can occur whenever conditions permit the growth of aflatoxin-producing fungi, although there is no evidence that the growth of aflatoxin-producing fungi always results in toxin production (reference 15). Aflatoxins may be found even when mold

growth is not visually obvious or has been obscured by blending or processing. Therefore, the presence and concentrations of aflatoxins must be determined by chemical analysis for the aflatoxins themselves.

Although improper storage or inadequate drying of corn can cause growth of aflatoxin-producing molds after harvest, investigation into the causes of aflatoxin contamination has shown that contamination of corn frequently occurs prior to or during harvest. Insect damage, environmental stresses (e.g., drought and hail), and plant variety have also been shown to increase susceptibility of corn to mold growth (reference 16).

Until the environmental and agronomic factors relating to aflatoxin contamination are better understood and agricultural practices are adjusted to better control mold growth in the field, there will continue to be some level of aflatoxin contamination in corn and other susceptible commodities.

SUMMARY OF IMPACT ON NATIONAL FOOD SUPPLY

Aflatoxin contamination of the 1980 corn crop has reached disastrous proportions in the states of North and South Carolina and is significant in the Commonwealth of Virginia. Data included with the exemption requests from the States indicate that 63 percent of North Carolina's, 73 percent of South Carolina's, and up to 23 percent of Virginia's 1980 corn crop exceeds the 20 ppb action level. Data from other southeastern states indicate there may be a significant problem with aflatoxin contamination of 1980 harvested corn for the entire region (references 15 and 16) which may result in requests from other States for similar exemptions.

Due to the severe aflatoxin contamination of the 1980 corn crop in these states, much of their corn harvest could not be legally marketed in interstate commerce. By allowing these three states the use of blended or nonblended corn with aflatoxin levels not exceeding 100 ppb, it is anticipated that the available corn will be increased by approximately 101.4 million bushels, valued at 319.5 million dollars at current market prices.

CONCLUSIONS

Safety—Based upon all available evidence, the limited exemptions to the existing aflatoxin action level for feed corn will not result in an increased risk to the health of animals fed such corn, or to humans consuming edible tissues derived from those animals; and therefore, will not result in a significant health hazard for humans or other animals. It may also relieve local pressures to use contaminated corn for milling into food or dairy rations. These exemptions shall be applicable only to corn from the 1980 crop harvested in North Carolina, South Carolina and Virginia for consumption by mature, non-lactating livestock and mature poultry. Safety considerations dictate that corn moving in interstate commerce contain no more than 100 ppb.

National Food Supply—The destruction or diversion of corn required by the existing action level would result in a substantial adverse impact on the national food supply. Under the limited exemptions, the marketable feed corn from the 1980 crop in North and South Carolina and Virginia will be substantially increased.

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17. Memo—"Florida State Evaluation of Aflatoxin Problem—1980 Corn Crop" September 30, 1980.

18. Memo—"1980 Corn Crop." September 12, 1980.

EXHIBIT 9

CA 80-31 EX 9

DEPARTMENT OF HEALTH, EDUCATION
AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

NOV 28, 1980

Ms. Ellen Haas
Director
Ms. Thomas B. Smith
Research Director
Consumer Division
Community Nutrition Institute
1146 19th Street, N.W.
Washington, D.C. 20036

Dear Ms. Haas and Mr. Smith:

This responds to your letter dated October 6, 1980, expressing concern about proposals submitted to FDA by the States of North and South Carolina. These proposals request FDA to temporarily exempt corn produced in certain regions of the U.S. from our current action level for aflatoxin of 20 ppb when such corn is shipped in interstate commerce and to permit blending of corn to achieve levels of no more than 100 ppb aflatoxin provided certain conditions are met. These proposals, an additional one from Virginia, and the plans for controlling interstate shipments of corn containing not more than 100 ppb aflatoxin have now been approved. I understand that you have been sent copies of our responses to North and South Carolina which detail the stringent conditions under which the corn shipments will be allowed. We will shortly be publishing in

the *Federal Register* a notice stating the limited exemptions from the prohibition of interstate shipment and blending of corn containing more than 20 ppb aflatoxin.

I want to assure you that this Agency is committed to the protection of the public health. In reaching a decision on this matter, we have considered whether the corn is safe for consumption and whether destruction or diversion of the corn would have a substantial impact on the national food supply. (See the enclosed copy of 21 CFR 509.8.) Our decision has taken into account all available scientific evidence. The protection of the public health was—and remains—our main concern.

Your letter quotes several articles, studies, and reports which you believe support your present concern over the feeding of corn containing up to 100 ppb of aflatoxin to mature, non-lactating livestock and poultry. I would like to address some of the issues you have raised, in the context of the factors we considered in arriving at our decision.

Our overall policy on aflatoxin is still to reduce human exposure to as low a level as is technologically feasible; our decision concerning the 1980 corn harvest is consistent with this policy. Aflatoxins may occur naturally in certain products such as corn, most often as a result of adverse weather conditions. They can also occur as a result of improper harvesting and storage procedures, which can be controlled by man; efforts are continually being made to improve these procedures. Investigators are exploring safe methods of removing aflatoxin from these products. One of the most effective means founds thus far is the consumption of aflatoxin-contaminated feed by animals that metabolize aflatoxin very rapidly.

In your letter, you cite an article by Rodricks and Stoloff which delineated various feed/edible tissue ratios for aflatoxin. The feed/tissue ratios listed were instrumental in determining the best procedure for feeding

the aflatoxin-contaminated feed. As a practical matter, exposure to the maximum allowable level during the full course of feeding is not likely. *Controlled* feeding of corn containing no more than 100 ppb aflatoxin to mature non-lactating livestock and poultry is an effective way of removing aflatoxin from the corn and preventing the corn from adversely affecting human and animal health – while at the same time receiving the benefits of the use of the corn in maintaining an adequate food supply.

As you mentioned in your letter, aflatoxin is a potent carcinogen, with species susceptibility from levels as low as 0.1 ppb in trout. Several metabolites resulting from ingestion of aflatoxin-contaminated foods and feeds have been identified and the comparative toxicities established. Because such information is not available for man, assessment of human toxicity from aflatoxin is based on extrapolation of animal data. Epidemiological studies on the incidence of primary liver cancer in Southeast Asia and Central Africa have shown a possible association with the consumption of aflatoxin contamination in foods. Unfortunately, all potential causes of liver cancer could not be adequately identified in these studies. Data obtained from the National Center for Health Statistics on death due to primary liver cancer from all sources in the U.S. (attached) do not show an increased incidence for the area in question where aflatoxin contamination of foods and feeds is an annual problem. Such studies highlight the difficulty is assessing the actual risk posed to man from aflatoxin contamination.

Your letter expresses specific concern that if interstate movement of corn containing up to 100 ppb aflatoxin is allowed, such corn will inevitably finds its way into all commercial channels, including human food and dairy feed uses. On the contrary, we believe that a *controlled* plan for utilization of such corn provides the growers and elevators with a legitimate outlet for this corn, in lieu of

destruction, and will most probably eliminate the incentive for unscrupulous business interests and the hard-pressed growers to divert this corn to concerns that may manufacture human foods or dairy feeds. We have no way of knowing whether corn shipped under the controlled plans will be discounted, but we suspect that without the plan, price reduction of contaminated lots would be inevitable.

Your letter correctly notes that we have stated in the past that we do not have the resources necessary to *routinely* (emphasis added) control the ultimate use of all corn moving in interstate commerce and have steadfastly refused all requests to raise the action level to 100 ppb across the board. Under the plans thus far approved for North and South Carolina and Virginia, the ultimate use of the shipments of corn containing up to 100 ppb aflatoxin will be controlled by the cooperating States. The plans will specifically delineate the state agencies responsible for monitoring the shipments, require written assurance from the ultimate user before shipment that the corn will only be fed to mature non-lactating livestock or poultry, and require documentation that the shipment (previously labeled and appropriately sealed) reaches the ultimate user. We will monitor selected shipments to determine compliance with the plan, and we will document the appropriate end use of these shipments. If we determine that the plans are not working properly, the temporary exemption will immediately be rescinded.

We would like to point out that an integral part of these plans is the assurance that the corn to be shipped interstate does not exceed 100 ppb as determined before shipment is allowed. This assurance is obtained through a thorough sampling of each lot (if a lot is blended, sample size is doubled) and the shipment is rejected if 80 ppb (average of duplicate analyses) or more of aflatoxin is detected. In addition, if a firm wishes to blend lots to obtain a final aflatoxin level below 100 ppb, proposals must be sub-

mitted by each firm and approved by the States separately. These plans must delineate the method of blending, the aflatoxin levels of the two lots to be blended, sampling procedures during or after blending, and the final analyses of the blended lot.

To sum up, we believe there is ample scientific evidence which demonstrates that corn containing up to 100 ppb of aflatoxin can be safely fed to mature, non-lactating livestock and poultry. This level provides a sufficient margin of safety to ensure that there will be no harmful effects on animal health or unsafe residues in edible tissues. The approved plans allow further assurance, through a statistically designed sampling plan and rejection limit of 80 ppb, that each lot actually contains no more than 100 ppb. Additional assurance is provided by the results of approximately 1,000 samples of liver—beef, swine and poultry—and eggs collected by the Food Safety and Quality Service of USDA from October 1977 to October 1978, the period of time when the contaminated 1977 corn crop was being used. These samples were collected at a rate of 120 per month; no aflatoxin was detected in any sample. (Current methodology can detect approximately 0.1 ppb aflatoxin, depending on the product.)

We firmly believe that the controlled feeding of this corn to mature, non-lactating livestock and poultry is an effective means of reducing human exposure to aflatoxin and is an appropriate course of action in emergencies such as this. We repeat that we have not compromised the public health and, in fact, are making every effort to protect it without drastically affecting the food supply in this country.

Sincerely yours,

/s/

Jere E. Goyan
Commissioner of Food and Drugs

Enclosures

§ 509.8 Exemptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a notice in the FEDERAL REGISTER and public comment shall be invited on the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies, e.g., the specific growing area or other identifying information. The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon the request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

Mortality From Primary Liver Cancer by Region, by Race, by Locale from XCHS data tapes 1968-71, 1973-76

	White				Negro				Japanese		Chinese		Hawaiian	
	Male		Female		Male		Female		Male	Female	Male	Female	Male	Female
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural						
[(age 30-50 liver cancer deaths/all deaths)/10^5]														
Appalachia	7	13	10	7	15	6	7	8						
Delta	11	3	3	9	21	16	7	8						
Dist. Columbia	0		0		54		17							
Downeast	3	7	3	4										
Hawaii	0	0												
Midwest	7	6	6	8	43	15	16	20						
Mountain	10	6	4	8	17									
North Plains	4	6	10	6	16		0							
Northeast	7	8	5	9	31	25	17	17						
Northwest	10	3	3	13	140		0							
South Border	6	9	3	3	30	7	8	5						
South Plains	14	7	11											

Table – Continued

	White				Negro				Japanese		Chinese		Hawaiian	
	Male		Female		Male		Female		Male	Female	Male	Female	Male	Female
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural						
[(age 30-50 liver cancer deaths/all deaths)/10^5]														
Southeast	8	7	4	6	32	14	6	9						
Southwest	8	10	7	8	34	32	20	79						
All Areas	8	7	6	8	36	16	14	10	84	22	377	119	135	38
[(all liver cancer death/all deaths)/10^5]														
Appalachia	132	138	114	103	252	141	98	90						
Delta	147	100	66	69	131	105	39	47						
Dist. Columbia	120		81		364		160							
Downeast	89	79	73	45										
Hawaii	201	92	204	77										
Midwest	131	92	84	80	281	166	125	103						
Mountain	91	72	63	66										
North Plains	95	117	88	110	135		85							

Table – Continued

	White				Negro				Japanese		Chinese		Hawaiian	
	Male		Female		Male		Female		Male	Female	Male	Female	Male	Female
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural						
	[(all liver cancer deaths/all deaths)/10^5]													
Northeast	136	117	76	83	225	122	98	85						
Northwest	115	98	79	87	280		48							
South Border	109	99	68	51	229	106	104	78						
South Plains	194	160	150	140	284	259	154	104						
Southeast	127	106	79	82	167	84	63	46						
Southwest	136	125	77	83	198	303	104	210						
All Areas	134	110	84	85	232	118	100	64	560	333	1,682	595	581	510
	[total deaths in 1,000's]													
Appalachia	120	250	102	173	34	16	29	12						
Delta	89	159	72	108	47	64	40	51						
Dist. Columbia	12		12		24		18							
Downeast	31	67	29	53										
Hawaii	4	2	3	1										

Table – Continued

	White				Negro				Japanese		Chinese		Hawaiian	
	Male		Female		Male		Female		Male	Female	Male	Female	Male	Female
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural						
	[total deaths in 1,000's]													
Midwest	1,049	922	698	692	180	13	133	9						
Mountain	92		74											
North Plains	82	114	70	162	6		5							
Northeast	1,149	684	1,021	559	163	16	126	12						
Northwest	112	115	92	75	4		2							
South Border	103	167	88	127	47	30	35	21						
South Plains	289	230	230	163	50	22	39	17						
Southeast	317	453	250	325	115	125	96	96						
Southwest	544	222	464	154	46	6	35	4						
All Areas	3,991	3,521	3,404	2,590	718	294	559	222	12	9	12	5	4	3

(KY.TN,WV) Delta (AR, LA, MS) Downeast (ME,VH.VT) Midwest (IA, IL, IN, MI, MN, MO, OH, WS) (D, MT, UT, WY) North Plains (KS, NB, ND, SD) Northeast (CT, MA, NJ, NY, PA, RI) DR,WA) South Border (DE, MD, VA) South Plains (NM, OK, TX) Southeast (AL, FL, GA, NC, SC) Southwest (AR, CA, NV)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEFENDANT.

STATEMENT OF LEONARD STOLOFF

1. I, Leonard Stoloff, am a Research Chemist in the Division of Chemistry and Physics, Bureau of Foods, United States Food and Drug Administration ("FDA"). My curriculum vitae and a list of my scientific publications are attached.

2. Since 1963, I have been involved in the supervision and performance of research on the analysis, properties, and occurrence of toxicants produced by fungi (mycotoxins), particularly the aflatoxins. Since 1970, I have been manager of the FDA, Bureau of Foods projects "Mycotoxins Literature," and "Control of Mycotoxins in Foods" As manager of the first project, I have been responsible for maintaining a current awareness of all ongoing and published research concerned with mycotoxins, accomplished through a well-developed information gathering network and an interacting computer system for citation storage. As manager of the second project, I have been responsible for translating the acquired information into rational programs for control of mycotoxins, particularly aflatoxin. I have, in this capacity, been responsible for the major portion of the technical input for the FDA programs for control of aflatoxins.

For a list of my contributions to the knowledge of aflatoxins and my participation in groups outside of FDA that are concerned with aflatoxins, see the attached list of special invitations and of publications.

3. The term aflatoxin(s) refers to a group of chemically related substances designated as B_1 , B_2 , G_1 , and G_2 , that are produced by certain common molds. The major member of the group is called Aflatoxin B_1 . Aflatoxin B_1 is a toxic chemical which causes liver damage in animals.

The term aflatoxin(s) also is used to designate any of several aflatoxin metabolites produced in animals receiving contaminated feed. The principal such metabolite of concern is aflatoxin M_1, a derivative of B_1 that can be formed in lactating animals and excreted in their milk.

4. Current knowledge supports the conclusion that corn containing as much as 100 ppb aflatoxin B_1 does not present a reasonable possibility of injury either to the health of mature, nonlactating livestock (beef cattle or swine) or mature poultry or to the health of humans who consume meat or eggs derived from these animals.

5. In the United States the levels of aflatoxin in corn vary from region to region and within regions, from year to year.

6. Prior to 1977, various surveys by the United States Department of Agriculture and Food and Drug Administration indicated that approximately 30% of the shelled corn grown and marketed in the Southeast had total aflatoxin levels exceeding the 20 ppb action level.

7. Food and Drug Administration surveillance of the 1977 shelled corn crop marketed in the Southeast found 64% of the samples with aflatoxin levels which exceeded 20 ppb and 40% which exceed 100 ppb.

8. Food and Drug Administration surveillance of shelled corn in the Southeast found 33% of the 1978 and 1979 crop samples to be above 20 ppb aflatoxin and 18% to be above 100 ppb.

9. Based upon preliminary data provided by states in the Southeast regarding the 1980 corn crop, 44% of the crop samples exceed 20 ppb aflatoxin and 8% exceed 100 ppb.

10. Based upon preliminary data obtained from Food and Drug Administration surveillance of the 1980 corn crop, 40% of the crop samples exceed 20 ppb and 33% exceed 100 ppb.

11. United States Department of Agriculture and Food and Drug Adminstration surveys since 1964 have found negligible aflatoxin contamination in corn harvested in the Midwest.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing statement is true and correct.

Executed on April ____, 1982.

LEONARD STOLOFF
Research Chemist
Division of Chemistry and Physics
Bureau of Foods
United States Food and Drug Administration
Washington, D.C.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEFENDANT.

PLAINTIFFS' RESPONSE TO DEFENDANT'S STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE DISPUTE

Plaintiffs refer the Court to their statement of material facts and specifically respond to defendant's statement as follows:

1. Plaintiffs deny the factual assertions contained in the first sentence of paragraph 11, but dispute that this is a fact material to the issues involved in this suit. The question of the safety of any tolerance level should be addressed in a rulemaking proceeding in which the public is involved. The issues in this suit concern plaintiffs' effort to assure public participation in FDA's tolerance-setting activities.

2. Plaintiffs dispute that the last sentence in paragraph 12 and paragraphs 16 and 17 are material to the issues in this case, for the reasons stated in plaintiffs' opposition to defendant's motion for summary judgment at pp. 11-18.

Respectfully submitted,

/s/

Diane B. Cohn
William B. Schultz
Alan B. Morrison
2000 P Street, N.W., Suite 700
Washington, D.C. 20036
(202) 785-3704
Attorneys for Plaintiffs

May 17, 1982

Food and Drug Administration

[Docket No. 83-D-0371]

Aflatoxin-Contaminated Corn; FDA's Policy Regarding Interstate Shipment of Corn Harvested in 1983

AGENCY: Food and Drug Adminstration.

ACTION: Notice.

SUMMARY: This document announces the policy of the Food and Drug Administration [FDA] regarding interstate shipment of corn harvested in 1983 that contains aflatoxin in excess of the agency's current action level of 20 parts per billion [ppb]. Because there is a severe aflatoxin problem in the 1983 corn crop, FDA will not object to the shipment of corn containing between 20 to 100 ppb aflatoxin in interstate commerce provided reasponsible State agencies have in place a control plan that has FDA concurrence and that assures that such corn is used only in feeds for mature beef cattle, swine and poultry and that such corn is not diverted for dairy or immature animal feed use or direct human food use. As part of this policy, FDA is carrying out regulatory surveillance to ensure that State control efforts are effective.

DATES: This policy became effective November 9, 1983. This policy applies only to corn harvested in 1983 and will remain in effect until January 1985.

ADDRESS: Written comments to the Dockets Management Branch [HFA-305], Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John R. Wessel, Office of Regulatory Affairs [HFC-6], Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1815.

SUPPLEMENTARY INFORMATION: Based on the available information, the 1983 corn crop of the southeastern States shows a high incidence of aflatoxin contamination above the FDA action level of 20 ppb.

Weather conditions (i.e., drought and high humidity) similar to those which contributed to the aflatoxin problem in the Southeast also existed this year in other parts of the country. Preliminary information indicates that this year's aflatoxin problem in corn also extends beyond the Southeast.

In previous years when a severe aflatoxin/corn problem existed, the agency advised individual States that corn containing up to 100 ppb aflatoxin could be fed safely to mature nondairy livestock and poultry (46 FR 7447, January 23, 1981; 43 FR 14122, April 4, 1978). This advise was based on available scientific information which indicated then, as now, the aflatoxin levels up to 100 ppb in feed would not be detrimental to the health of mature beef cattle, swine, and poultry or result in toxicologically significant residues of aflatoxin in foods derived from these animals. Implementation of this policy was, however, contingent upon the States agreeing to exercise controls that prevented use of corn containing above 20 ppb aflatoxin for direct human food use for feeding to dairy cattle or immature animals. This control was necessary because FDA believed, and still believes, that the consumption of corn and corn products containing aflatoxin in excess of 20 ppb poses a health risk to humans and immature animals and, if fed to dairy cattle, may result in unsafe aflatoxin residues in milk.

In responding to the 1983 aflatoxin-corn situation, the agency has adopted a regulatory policy similar to that of past years. Accordingly, the agency advised the Departments of Agriculture in all States by letter dated November 9, 1983 that it will not object to corn containing between 20 and 100 ppb aflatoxin moving in interstate commerce provided responsible State officials have in place a control plan that has FDA concurrence and that assures that (1) such corn will be used only in feed for mature beef cattle, swine, and poultry; and (2) such corn

will not be diverted to feeds for dairy or immature animals or be used in the processing of corn products for human consumption.

States that choose to adopt this policy for their 1983 corn crop may design their own control plan; however, FDA has specified minimum provisions that each State control plan should contain.

Each affected State should notify FDA whether it wishes to adopt the policy and whether it is committed to and able to carry the necessary controls. States wishing to cooperate under the policy are to submit their proposed control plans to FDA for review and concurrence.

As part of a national enforcement program, FDA will be sampling corn in interstate commerce with emphasis given to corn that will be used by corn product manufacturers and dairy farms, and to States not participating in the cooperative program. FDA will also be testing milk and milk products for aflatoxin.

Because FDA's policy provides the States and the corn industry with the opportunity to channel corn containing up to 100 ppb aflatoxin into those animal feed uses that are considered safe, the agency believes it should help relieve pressures at the local level to process such corn into human food or to use it as feed for dairy animals. For this reason, FDA has also encouraged States to adopt a similar policy and control plan for corn produced and used only within their States. Additionally, States are being urged to monitor corn and corn products intended for human consumption, and to monitor milk for compliance with the 20 ppb and 0.5 ppb action levels, respectively.

Documents and correspondence related to this notice are on file with the Dockets Management Branch (address above).

Interested persons may submit comments on this notice to the Dockets Management Branch (address above). Two copies of any comments are to be submitted except that

individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 1983

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.
[FR Doc. 83-31723 Filed 11-23-83; 8:45 am]
BILLING CODE 4160-01-M

PUBLIC CITIZEN LITIGATION GROUP
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December 16, 1983

Joseph P. Hile, Associate Commissioner
for Regulatory Affairs
Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 4-62
5600 Fishers Lane
Rockville, Md. 20857

Re: Aflatoxin in Corn
Docket No. 83-D-0371

Dear Mr. Hile:

These comments are submitted in response to the notice published at 48 Fed. Reg. 53175 (November 25, 1983), announcing the FDA's policy of permitting the shipment of corn containing aflatoxin levels up to 100 ppb. The comments are submitted on behalf of the Community Nutrition Institute ("CNI"), Public Citizen Health Research Group ("HRG"). Linda S. Bardot, Laura A. Rogers, and Public Voice for Food and Health Policy ("Public Voice"). All the submitters except Public Voice are plaintiffs in *Community Nutrition Institute v. Hayes,* Civil Action No. 80-3110, a case pending in the United States District Court for the District of Columbia, which challenges the FDA's policies with respect to aflatoxin. Public Voice is a public interest organization which was founded since the filing of that lawsuit and which is dedicated to promoting policies which will improve the safety and quality of the nation's food supply.

The purpose of these comments is to lodge a formal objection to the FDA's new policy of increasing the allowable levels of aflatoxin in corn to 100 ppb. We have stated the basis for our objection to the FDA's policy with respect to aflatoxin on numerous occasions. Specifically, we refer to and incorporate by reference comments filed by HRG on February 24, 1975; comments filed by CNI on October 6, 1980; comments filed by CNI and HRG on September 29, 1983; and the two legal memoranda filed by plaintiffs in the *Community Nutrition Institute v. Hayes* lawsuit. The comments are already on file with the agency, but we are attaching the legal memoranda for your information.

We wish to emphasize, as we have on numerous occasions our position that the FDA may not sanction the shipment of food with any amount of aflatoxin until it has complied with the formal rulemaking procedures in sections 406 and 701(e) of the Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 346, 371(e), or at least the informal rulemaking requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553. We hereby reiterate our request that the FDA use the formal rulemaking procedures in section 406 to establish the legal levels of aflatoxin in corn, or in the alternative, the informal rulemaking procedures in the APA. *See* Memorandum in Support of Plaintiffs' Motion for Summary Judgment, pp. 11-20.

We also belive that the FDC Act requires an opportunity for public participation before the FDA may raise the allowable level of aflatoxin in corn from 20 ppb to 100 ppb, as it has done here. As our authority for this contention, we rely on the sections of the FDC Act and the APA cited above, as well as the authorities cited in the attachments to these comments.

Sincerely yours,

/s/
William B. Schultz

Enclosures
cc: Dr. Mark Novitch, Commissioner

234

Supreme Court of the United States

No. 85-664

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ORDER ALLOWING CERTIORARI. Filed December 9, 1985.

The petition herein for a writ of certiorari to the United States Court of Appeals for the District of Columbia Circuit is granted.

U.S. GOVERNMENT PRINTING OFFICE: 1986—491-507/20513

13

Supreme Court, U.S.
FILED
FEB 10 1986
JOSEPH F. SPANIOL, JR.
CLERK

No. 85-664

In the Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG,
COMMISSIONER OF FOOD AND DRUGS, PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE PETITIONER

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68 pp

QUESTION PRESENTED

Whether the Food and Drug Administration is required to regulate unavoidable "added" poisonous or deleterious substances in food by means of formal rulemaking pursuant to 21 U.S.C. 342(a)(2)(A), rather than by case-by-case adjudication pursuant to 21 U.S.C. 342(a)(1).

PARTIES TO THE PROCEEDING

The petitioner is Frank Young, Commissioner of Food and Drugs. The respondents are the Community Nutrition Institute, Public Citizen, and Linda S. Bardot.

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In the Supreme Court of the United States

OCTOBER TERM, 1985

No. 85-664

FRANK YOUNG,
COMMISSIONER OF FOOD AND DRUGS, PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-16a) is reported at 757 F.2d 354. The May 1, 1985, order amending the court of appeals' opinion (Pet. App. 17a) and the opinion of the district court (Pet. App. 21a-34a) are unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 35a) was entered on March 26, 1985. A petition for rehearing was denied on May 23, 1985 (Pet. App. 18a). By order dated August 13, 1985, Justice Brennan extended the time within which to file a petition for a writ of certiorari to and including October 20, 1985. The petition was filed on October 18, 1985, and was granted on December 9, 1985. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Sections 402(a), 406, and 701(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a), 346, and 371(e), and 21 C.F.R. 509.6(b)-(c) are reproduced in an appendix to this brief. App., *infra*, 1a-5a.

STATEMENT

A. Introduction

This case concerns the procedures that the Food and Drug Administration (FDA) must employ in regulating the presence in food of any added poisonous or deleterious substance that is required in the production of the food or that cannot be avoided by good manufacturing practices. Specifically at issue here are "aflatoxins," a group of chemically-related substances produced as natural by-products of the growth of certain common molds on corn and other crops. Aflatoxins exhibit cancer-producing properties in some species of experimental animals, and epidemiological studies on certain population groups in Southeast Asia and Africa indicate that direct consumption of aflatoxin-containing foods may also be associated with primary liver cancer in humans. J.A. 35-37, 169, 203; Pet. App. 3a. However, these studies cannot identify all potential causes of the disease (J.A. 214), and there is no direct evidence that aflatoxin causes primary liver cancer in man. J.A. 35, 46. Data from the National Center for Health Statistics on deaths due to such cancer from all sources in the United States do not show an increased incidence in areas where aflatoxin contamination is an annual problem. J.A. 214, 218-221.

Aflatoxins may contaminate foods whenever environmental conditions are such as to favor the growth of the producing molds. Favorable growth conditions often exist naturally in the field where susceptible crops are growing. Such conditions also can be created when crops are improperly stored. See J.A. 207-208. Human intervention can prevent the problem in the latter situation,

but preventative action is largely ineffective in the case of field contamination, because the contamination occurs before or during harvest. Thus, complete elimination of aflatoxin from susceptible commodities, such as corn, cottonseed, peanuts, and tree nuts, is not currently possible. See J.A. 39, 43, 44, 208; 39 Fed. Reg. 42748 (1974). Moreover, residues of aflatoxin can appear in the edible tissues, eggs, and milk of animals fed aflatoxin-contaminated corn, cottonseed, and other feeds, and there is no known method for removing aflatoxin residues from such products. J.A. 207. For all these reasons, the FDA has treated aflatoxin as a poisonous or deleterious substance and has taken steps to limit human and animal exposure to aflatoxin-tainted food to the greatest extent feasible. 39 Fed. Reg. 42749 (1978); J.A. 187, 207.

Since the enactment of the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938, 21 U.S.C. 301 *et seq.*, the Commissioner of Food and Drugs, as the designee of the Secretary,[1] has regulated the amount of substances like aflatoxin principally by using publicly available prosecutorial guidelines that the FDA terms "action levels."[2] These action levels announce the amount of a particular added poisonous or deleterious substance that the FDA regards as resulting in adulteration under Section 402(a)(1) of the FDCA, 21 U.S.C. 342(a)(1). Food containing such a substance in excess of the action level is subject to an enforcement action by the United States. In this case, the court of appeals upset this longstanding administrative construction of the FDCA, holding that the FDA may not proceed by means of action levels but must instead set "tolerances" by time-consuming and burdensome formal rulemaking procedures.

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[1] Pursuant to Section 701(a) of the FDCA, 21 U.S.C. 371(a), and under the authority delegated to him by the Secretary (21 C.F.R. 5.10), the Commissioner of Food and Drugs is authorized to enforce the FDCA.

[2] The FDA's action levels have been publicly available since 1972. Prior to that time, the agency's action levels were generally treated as confidential internal policy matters. See 37 Fed. Reg. 6497 (1972). Current action levels are reprinted at J.A. 148-168.

B. The Statutory and Regulatory Framework

1. *The Statutory Definition Of "Adulterated" Food.* The FDCA prohibits the shipment in interstate commerce of "adulterated" food. 21 U.S.C. 331. A food is generally deemed to be "adulterated" due to the presence of a poisonous or deleterious substance, whether it is inherent in the food or is "added" to it,[3] if any one of three conditions is met. See 21 U.S.C. 342(a)(1) and (2)(A).[4] *First*, a food is deemed adulterated under the first clause of Section 402(a)(1) of the FDCA, 21 U.S.C. 342(a)(1), if it contains an added poisonous or deleterious substance "which may render it injurious to health."[5] *Second*, if a substance is inherent in a food (*i.e.*, is not "added"), then, under the second clause of Section 402(a)(1), food containing that substance is adulterated if the substance renders the food "ordinarily * * * injurious to health."[6] *Third*, a food is adulterated under Section 402(a)(2)(A), 21 U.S.C. 342(a)(2)(A), if it contains any "added poisonous or added deleterious substance * * * which is unsafe within the meaning of" Section 406, 21 U.S.C. 346. Aflatoxin fits within this last provision (as well as the first one); it is not an inherent constituent of food since it is added by mold. J.A. 34-35.

[3] The term "added" is not defined in the FDCA. The FDA's regulations define an "added" poisonous or deleterious substance as one that "is not a naturally occurring * * * substance" (21 C.F.R. 109.3(d), 509.3(d)), and, in turn, define a "naturally occurring poisonous or deleterious substance" as "a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination" (21 C.F.R. 109.3(c), 509.3(c)). See also 42 Fed. Reg. 52814-52816 (1977); 39 Fed. Reg. 42743-42744 (1974); J.A. 13-15, 55-56, 56-57, 61-63.

[4] The general adulteration standard set forth in Section 402(a)(1) is supplemented by other provisions containing more specific safety standards for pesticides (see 21 U.S.C. 346a), food additives (see 21 U.S.C. 348), color additives (see 21 U.S.C. 376), and new animal drugs (see 21 U.S.C. 360b).

[5] See *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 161 (1958); *United States* v. *Coca Cola Co.*, 241 U.S. 265, 277, 283 (1916); *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).

[6] See *Continental Seafoods, Inc.* v. *Schweiker*, 674 F.2d 38, 41 (D.C. Cir. 1982); *United States* v. *Anderson Seafoods, Inc.*, 622 F.2d 157, 159 (5th Cir. 1980).

Section 406 of the FDCA defines when a food with an added poison is "unsafe" within the meaning of that provision. The first clause of Section 406 provides that any added poisonous or deleterious substance renders the food unsafe unless its presence "is required in the production thereof or cannot be avoided by good manufacturing practice." Aflatoxin falls within this exception (see J.A. 187, 207), and food containing aflatoxin is therefore not rendered "unsafe" by this clause. However, Section 406 goes on to state:

> [W]hen such substance is so required or cannot be so avoided, the Secretary [of Health and Human Services] shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of [Section 342(a)(2)(A)].

Section 406 further provides that, while a regulation is in effect, food containing such a substance is not adulterated under Section 402(a)(1).

2. *The FDA's Use Of "Action Levels" And "Tolerances."* For nearly a half-century, the FDA has construed these provisions as allowing it to regulate substances such as aflatoxin either by exercising its prosecutorial discretion to bring enforcement actions under Section 402(a)(1), 21 U.S.C. 342(a)(1), or by issuing regulations ("tolerances") via formal rulemaking pursuant to Sections 406 and 701(e), 21 U.S.C. 346 and 371(e). If the FDA elects to proceed under Section 402(a)(1), the government must establish in an enforcement proceeding that the level of the added substance present may render the food injurious to health. This is the option that the FDA has used with respect to aflatoxin, and the FDA has

adopted an "action level" to aid in the exercise of its prosecutorial discretion. J.A. 150. In the alternative, the FDA may promulgate a tolerance under Section 406. Once a tolerance is in effect, the government in an enforcement proceeding need only establish that the tolerance has been exceeded; it need not adduce independent evidence that the food may be injurious to health. See 21 U.S.C. 342(a)(2)(A) and 346. Therefore, the use of action levels or tolerances affects only the government's elements of proof in an enforcement action. In either case, the contaminated food is subject to seizure (see 21 U.S.C. 334) and the person responsible for shipping the contaminated food in interstate commerce may be enjoined from causing such shipment (see 21 U.S.C. 332) and subjected to criminal sanctions (see 21 U.S.C. 333).

The FDA considers the same factors—*i.e.*, those set forth in 21 U.S.C. 346—in setting both action levels and tolerances. 21 C.F.R. 109.6 (human food); 21 C.F.R. 509.6 (animal feed).[7] However, the procedures employed in promulgating action levels differ significantly from those required for the issuance of tolerances. Action levels are not considered to be subject to the notice-and-comment rulemaking procedures of the Administrative Procedure Act.[8] Nonetheless, the FDA does publish a notice in the *Federal Register* announcing the new level and the availability of all the relevant data, and it invites public comment. See 21 C.F.R. 509.4(b)(2); 42 Fed. Reg. 52817 (1977).

By contrast, 21 U.S.C. 346, in conjunction with 21 U.S.C. 371(e), prescribes a formal and complicated pro-

[7] These factors include (1) the level necessary to protect the public health, (2) the extent to which the substance is unavoidable, (3) the effect of other poisonous or deleterious substances on the public health, and (4) the ability of analytical methods to detect and quantify the substance when it is discovered in food. 21 C.F.R. 109.6, 509.6; J.A. 21-22. The FDA considers the overall economic impact of the permitted level in connection with the second factor. See 42 Fed. Reg. 52816 (1977).

[8] Respondents challenged this practice below, but the court of appeals did not address the point (Pet. App. 2a).

cedure for the issuance of regulations setting, amending, or repealing tolerances for substances whose addition to food is required or unavoidable. The FDA must publish a proposed tolerance for public comment. 21 U.S.C. 371(e)(1). After evaluating the comments, the FDA must publish a "final order" to which objections can be filed, along with requests for a formal trial-type administrative hearing. *Ibid.* The filing of an objection accompanied by an adequate request for a hearing stays the effectiveness of the tolerance pending further notice in the *Federal Register* and the hearing itself (21 U.S.C. 371(e)(2)), at which "any interested person may be heard in person or by representative" (21 U.S.C. 371(e)(3)). Finally, following the completion of the formal administrative proceeding, including an initial decision by an administrative law judge and any subsequent appeal to the Commissioner of Food and Drugs, the FDA must issue an order setting forth "detailed findings of fact" and establishing the tolerance. *Ibid.* Except in emergencies, the regulation may not take effect until 90 days after the Commissioner's decision (*ibid.*), which is subject to judicial review in the court of appeals (21 U.S.C. 371(f)). In short, 21 U.S.C. 346 and 371(e) mandate a formal rulemaking procedure properly characterized as one of the more elaborate under which any federal agency must operate. See generally R. Merrill & P. Hutt, *Food and Drug Law* 895-896 (1980).

In determining whether to issue informal action levels or formal tolerances in a particular case, the FDA takes these procedural differences into account. Because of the exhaustive procedures necessary to establish a new tolerance or to modify an existing one, the FDA generally establishes tolerances only when their lifespan is expected to be relatively long. Accordingly, the FDA's regulations provide for the use of action levels in dynamic circumstances, *i.e.*, when it is impracticable to set tolerances. See 21 C.F.R. Pt. 109 (human food); 21 C.F.R. Pt. 509 (animal feed); J.A. 21, 68. The FDA uses action levels rather than tolerances when the extent to

which a substance is unavoidable may change yearly, when changes in the capabilities of good manufacturing practices are expected, or when current toxicological data are scanty or conflicting but the results of ongoing studies might provide significant new data or other information that would render a tolerance obsolete. 21 C.F.R. 109.6(b)-(c), 509.6(b)-(c); J.A. 21, 68-70. For instance, the FDA has used action levels to regulate the presence of aflatoxin in corn because the level of aflatoxin in corn varies from region to region, and within regions, from year to year. See J.A. 223-224. In these circumstances, a tolerance would be outdated shortly after its adoption. See J.A. 68.[9]

3. *The Exemption Process.* The FDA has recognized that in some circumstances the public interest may justify allowing certain food containing a substance in an amount in excess of an action level to be marketed. The FDA's regulations therefore allow the Commissioner to refrain from recommending enforcement action (*i.e.*, to grant an "exemption") in such circumstances. 21 C.F.R. 109.8(a)(1), 509.8(a)(1). The FDA has stated that an exemption will be granted only where "a large amount of food is contaminated, resulting in a substantial adverse impact on the national food supply, and all available toxicological data indicate that no significant health hazard is involved." 39 Fed. Reg. 42746 (1974); J.A. 24. An exemption applies only to the specific parties to whom it is granted and only to the particular food covered, and lasts only for a specified period of time. *Ibid.*

In 1965, the FDA set an action level for aflatoxin in human food and animal feed at 30 parts per billion (ppb).

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[9] See also *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149, 153 (5th Cir. 1979) ("[t]he statute does not demand rigid and permanent fixity in the numbers game, mainly because our social policies and scientific knowledge about dangerous food are not themselves steady and static"); *United States* v. *Goodman*, 486 F.2d 847, 854 (7th Cir. 1973) (finding that an in-depth consideration of tolerances for DDT when DDT levels in the environment were in a state of flux would be "virtually meaningless").

J.A. 37. The FDA reduced the action level to 20 ppb in 1969, and it has since remained at that level. *Ibid.*; *id.* at 135, 169, 170; Pet. App. 22a. However, in 1980 the levels of aflatoxin in corn harvested in several states were unusually high. In October and November 1980, in response to requests from Virginia, North Carolina, and South Carolina, the FDA temporarily increased to 100 ppb the action level for aflatoxin-contaminated corn harvested in those states that was intended for feeding to mature, non-lactating beef cattle, swine, or poultry. The agency also permitted blending (mixing) of corn containing more than 20 ppb aflatoxin with untainted corn to achieve a level of up to 100 ppb aflatoxin. The FDA found that, under the terms and conditions of the exemptions, the feed corn was safe for consumption and that the destruction or diversion of the feed would have resulted in a substantial adverse effect on the national food supply.[10] The exemptions were conditioned upon full

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[10] An FDA study, "Aflatoxin-Contaminated Corn, Limited Exemptions from Prohibition of Interstate Shipment and Blending, Assessment of Safety and Impact on the National Food Supply" (Dec. 1980) (J.A. 202-211), concluded that the largest portion of corn containing aflatoxin that was ingested by food-producing animals is eliminated in excreta. *Id.* at 203. Although residues of aflatoxin may be found in the edible tissues of those animals under certain circumstances, so long as the level of aflatoxin in corn fed to the animals identified in the text did not exceed 100 ppb, the level of aflatoxin in their edible tissues would not exceed 0.1 ppb, the lowest level that can consistently be identified and measured in tissues by available analytical methods. *Id.* at 203-206. The FDA thus concluded that the meat and eggs from animals eating corn containing 20-100 ppb aflatoxin were "safe" for consumption within the meaning of 21 C.F.R. 509.8, *i.e.*, that "all available toxicological data indicate that no significant health hazard is involved." 39 Fed. Reg. 42746 (1974).

In 1978, responding to a similar situation, the FDA temporarily authorized the blending of corn containing more than 20 ppb aflatoxin with untainted corn to achieve a level of up to 20 ppb aflatoxin and the subsequent interstate shipment of the blended corn. See 43 Fed. Reg. 14122 (1978). In 1983, the FDA allowed corn containing aflatoxin not exceeding 100 ppb to be shipped in interstate commerce for use as feed for certain animals, on the

compliance by the states and the affected industries with detailed control plans designed to ensure that the terms of the exemptions were satisfied. The FDA's decision not to recommend enforcement action was contingent upon such full compliance. See 46 Fed. Reg. 7447 (1981); J.A. 24, 114-122, 131-132, 189-190, 196-197, 199-201; Pet. App. 25a-26a. These exemptions, which expired on January 1, 1982, gave rise to this lawsuit. Pet. App. 25a, 26a.

C. The Proceedings Below

1. *The District Court's Decision.* Respondents (two public interest groups and a consumer) brought this suit in the United States District Court for the District of Columbia, challenging the FDA's regulation of aflatoxin.[11] Respondents did not allege that the FDA's 20 ppb action level was insufficient to protect the public health or had led to any serious health problem, that formal tolerances were necessary to protect the public health, or that the FDA was not adequately enforcing the FDCA (J.A. 109-112 (complaint)). Rather, they claimed (1) that the FDA should be ordered to adopt a formal tolerance for aflatoxin pursuant to Section 406, 21 U.S.C. 346, rather than to use an informally implemented action level, (2) that the action level, in the alternative, should be made subject to the notice-and-comment provisions of the Administrative Procedure Act, and (3) that the 1980 exemptions to the FDA's action level were contrary to law. J.A. 109-112 (complaint); see also *id.* at 169-171, 225-226.

The district court granted summary judgment in favor of the FDA on all three issues (Pet. App. 21a-34a).

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ground that the corn was not adulterated within the meaning of 21 U.S.C. 342(a)(1) for its intended use. See 48 Fed. Reg. 53175 (1983); cf. J.A. 193, 194, 225.

[11] In September 1980, respondent Community Nutrition Institute (CNI) learned that North Carolina and South Carolina had sought exemptions, and the following month CNI urged the FDA to deny these requests and any similar ones. The FDA rejected CNI's request on November 28, 1980, in a letter giving the reasons for the agency's decision. J.A. 212-216.

Recognizing that an agency's interpretation of the statute it is responsible for administering is entitled to substantial deference, the court ruled that the FDA's construction of Section 406 was reasonable and that Section 406 "confers discretionary, not mandatory, authority on the agency to establish tolerances" (Pet. App. 31a-32a (footnote omitted)). The court also concluded that "action levels" were general statements of policy not requiring notice-and-comment rulemaking and that the exemptions granted by the FDA were within the agency's discretion (*id.* at 32a-34a).

2. *The Court Of Appeals' Decision.* The court of appeals reversed, holding that "the FDA may not proceed by means of action levels rather than tolerances" (Pet. App. 2a).[12] The court relied heavily on its parsing of the second clause of Section 406, which provides that when an added poisonous or deleterious substance is "required" or "cannot be * * * avoided * * * the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health." The court refused to accept (Pet. App. 6a) the FDA's interpretation of this provision, *i.e.*, that the Secretary is obligated to promulgate formal regulations only " 'to such extent as he finds necessary for the protection of public health' " and may employ informal action levels in all other circumstances. Instead, the court found (*id.* at 7a) that it was "clear from the structure of the sentence * * * that the phrase relied upon by the Secretary simply does not modify the pivotal word 'shall' " but, rather, "explains the standard that the Secretary is to employ in setting the tolerance."

The court of appeals found additional support for its interpretation of the FDCA in an argument that suggests that most of the nation's food supply is "adulterated" within the meaning of the FDCA. The court construed (Pet. App. 7a) Section 406 to mean that any food to which an unavoidable poisonous or deleterious substance

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[12] Because the court of appeals reversed on this ground, it did not consider respondents' other claims (Pet. App. 2a).

has been added is adulterated unless "a regulation establishing a tolerance is in effect." The court reasoned (Pet. App. 7a) that, "[s]ince the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." The court advanced no other argument to buttress its interpretation. It found "little guidance in the legislative history" (*id.* at 9a), and it did not cite any supporting judicial authority, but instead merely attempted to distinguish the cases upon which the FDA relied (*id.* at 11a-15a).

INTRODUCTION AND SUMMARY OF ARGUMENT

In the production of food, it is often impossible to avoid the presence of negligible quantities of added substances that may be harmful to human health if taken in sufficient amounts.[13] For nearly 50 years, the FDA, with Congress's full awareness and the federal courts' approval, has regulated the presence of these substances in food principally by adopting informal "action levels" —*i.e.*, "in-house" guidelines used by the agency to inform its broad prosecutorial discretion (see *Heckler* v. *Chaney*, No. 83-1878 (Mar. 20, 1985))—and by relying on these prosecutorial guidelines in case-by-case litigation under Section 402(a)(1) of the FDCA, 21 U.S.C. 342(a)(1). This informal procedure has allowed the FDA to move quickly in response to health hazards; it has provided flexibility in an area in which the relevant scientific data and the capabilities of good manufacturing

[13] See, *e.g.*, 42 Fed. Reg. 52814 (1977) ("[t]he Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities. This is not a modern phenomenon. Wholesome foods have inevitably been the carriers of levels of contamination beyond the capability of contemporary processing methods to eliminate and sometimes even detect. At best, therefore, specifications for 'food grade' substances can be established * * * to ensure that only minimal levels of contaminating substances are present."); J.A. 55.

practices are subject to frequent and unforeseen modification; and it has permitted the FDA, by limiting burdensome and lengthy formal rulemaking proceedings, to allocate its scarce resources to activities of greater need in safeguarding the public health.

In this case, the court of appeals ruled that the FDA's historic regulatory practice is—and has been from the outset—ultra vires. Relying entirely upon a literal reading of statutory language that is ambiguous at best, and without regard for the statute's legislative history or purposes, the court held that the FDA is powerless to follow its settled practice because it has a mandatory duty under Section 406, 21 U.S.C. 346, to institute formal rulemaking proceedings to establish tolerances for added substances like aflatoxin. That ruling upsets the FDA's settled and successful practice and threatens both to squander administrative resources and to impair the FDA's ability to act expeditiously in response to changing conditions in this vitally important area. The court of appeals' reasoning also suggests that much of the nation's food supply is now and will remain "adulterated" within the meaning of the FDCA until formal regulations setting tolerances are issued, a process that is certain to take years, if not decades, to complete.

These unfortunate consequences need not be suffered, because the court of appeals' decision is plainly wrong. The court disregarded the well settled principle that an agency's construction of a statute that it is entrusted to administer is entitled to substantial deference. Here, the FDA's construction of Section 406 is fully consistent with the language, structure, and purposes of that and related sections of the FDCA. Moreover, a number of factors coalesce to show that the FDA's interpretation of the Act is entitled to particular deference.

1. a. By focusing on the term "shall" in Section 406, the court of appeals misconstrued the overall structure of the FDCA. Section 402(a)(1) establishes the general standard of adulteration and provides that a food is adulterated whenever an added poisonous or deleterious

substance may render the food injurious to health. Sections 406 and 402(a)(2)(A) provide that such an added substance automatically renders a food adulterated if the substance is not required in food production or is not unavoidable. Where neither condition obtains, Sections 406 and 402(a)(2)(A) deem a food to be adulterated only if it contains a poisonous or deleterious substance in excess of an existing tolerance; if no tolerance exists, a food is adulterated only if it may cause injury under Section 402(a)(1). The language of Section 406 contemplates the situation in which no tolerance is in effect by providing that "[w]hile such a regulation is in effect * * * food [containing an added poisonous or deleterious substance] shall not * * * be considered to be adulterated" under Section 402(a)(1). See *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 166 (1958). In the absence of a tolerance, Section 402(a)(1) governs.

The court of appeals' reading of Section 406 renders Section 402(a)(1) superfluous for added poisonous or deleterious substances that are required in food production or unavoidable. Sections 406 and 402(a)(2)(A) ban added poisonous or deleterious substances if they are *not* required or are *not* unavoidable. Thus, if the absence of a tolerance also bans such substances if they *are* required or *are* unavoidable, the FDA would never have occasion to resort to Section 402(a)(1) to prove that a food that contains such a substance is adulterated, despite the fact that Section 402(a)(1), like Sections 406 and 402(a)(2)(A), applies to added substances. The FDA's construction of Section 406, unlike the one adopted by the court of appeals, therefore gives effect to Sections 402(a)(1) and 406 for added substances like aflatoxin.

b. The legislative background of Section 406 reveals that Congress enacted this provision to empower the agency to select alternative ways of proving that a food is adulterated. The predecessor to the FDCA (the Federal Food and Drugs Act of 1906) required the FDA to prove in court in each case that a particular food posed

a risk of injury to a consumer's health. *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914). Section 406 was designed to allow the agency to adopt legislative rules fixing precise levels of forbidden contaminants for a broad range of added substances that, if exceeded, automatically rendered a food adulterated. Congress did not intend that the FDA must promulgate tolerances to enforce the adulteration provisions of the FDCA; on the contrary, Congress retained the provision of the original Federal Food and Drugs Act that allowed the agency to prove on a case-by-case basis that a food containing an added substance was unsafe. Both the agency, which drafted the original version of the FDCA, and Congress used the verbs "shall" and "is authorized to" interchangeably throughout Congress's consideration of the FDCA. And no witness who testified during the lengthy legislative consideration of the FDCA suggested that tolerances would be the exclusive means of enforcing the food adulteration provisions of the Act.

2. The FDA's construction of Section 406 is entitled to special deference for several reasons. First, the agency played an important role in drafting the statute. Second, for nearly a half-century, beginning almost immediately after passage of the FDCA, the FDA has consistently read this section as providing the agency with the discretion to promulgate tolerances. Third, Congress has been made aware of the agency's position and has done nothing to require the FDA to alter its historic regulatory practice; in fact, Congress relied on the agency's views when enacting amendments to the FDCA. Fourth, depriving the FDA of the discretion whether to enforce the statute by relying upon action levels and bringing enforcement actions or by setting tolerances would hamper the agency's ability to respond quickly to new toxicological data or changes in manufacturing practices and would divert the agency's limited resources from matters of greater need in the protection of the public health.

ARGUMENT

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AUTHORIZES THE COMMISSIONER OF FOOD AND DRUGS TO REGULATE UNAVOIDABLE ADDED POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD BY MEANS OF CASE-BY-CASE ADJUDICATION OR BY FORMAL RULEMAKING

It is a familiar and well-established principle of administrative law and statutory construction that an agency's interpretation of a statute that it is entrusted to administer is entitled to considerable deference from the courts. See, *e.g.*, *United States* v. *Riverside Bayview Homes, Inc.*, No. 84-701 (Dec. 4, 1985), slip op. 9; *Chevron U.S.A. Inc.* v. *NRDC*, No. 82-1005 (June 25, 1984), slip op. 4-7. A court is not free to overturn the agency's interpretation simply because the court may prefer a different one or because reasonable persons may differ as to the statute's meaning. Rather, so long as the agency has reasonably sought to implement a congressional policy rather than embark on a frolic and detour of its own, the agency's interpretation must be upheld. See, *e.g.*, *Riverside Bayview Homes*, slip op. 9-10, 17; *Chevron*, slip op. 5-7 & nn. 11-14; *Aluminum Co. of America* v. *Central Lincoln Peoples' Utility District*, No. 82-1071 (June 5, 1984), slip op. 8.

Under that standard, the FDA's contemporaneous and longstanding interpretation of Section 406 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346, should have been sustained. First, for the reasons given in Point A below, in light of the structure, purposes, and legislative history of the FDCA, it is entirely reasonable for the FDA to construe Section 406 as discretionary, rather than mandatory. Second, for the reasons explained in Point B below, a variety of factors make this a particularly compelling case for affording deference to the FDA.

A. The FDA's Interpretation of 21 U.S.C. 346 Is Consistent With The Text, Legislative History, And Purposes Of The Federal Food, Drug, And Cosmetic Act

As the court of appeals recognized, the pivotal statutory provision is the second clause of Section 406, 21 U.S.C. 346. It provides that when any added poisonous or deleterious substance is "required" in the production of food or "cannot be avoided by good manufacturing practice," the Commissioner of Food and Drugs "shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health." In the FDA's view, the phrase "to such extent as he finds necessary for the protection of the public health" modifies the verb "shall." So read, Section 406 provides that the agency must promulgate regulations only if it finds that doing so is necessary to protect the public health. Put another way, the statute means that the FDA *can* promulgate tolerances, not that the agency *must* do so. See *Webster's New Collegiate Dictionary* 1058 (1981) (noting these alternative definitions of "shall"). The FDA has long interpreted this section to mean that the agency is empowered, not required, to issue formal tolerances to enforce the adulteration provisions of the FDCA. See, *e.g.*, *Trade Correspondence* 136 (Mar. 7, 1940), *reprinted in* 1 V. Kleinfield, C. Dunn & A. Kaplan, *Federal Food, Drug, and Cosmetic Act Judicial Record 1938-1964*, at 622 (Food and Drug Law Inst. 1978).[14]

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[14] As the FDA there stated (emphasis added):

> The Administration, in the enforcement of old Food and Drugs Act, never announced formal tolerances for these substances in foods since no authority existed in the old law for so doing. The law * * * merely classified a food as adulterated if it contained any added deleterious ingredient which might render food injurious to health, leaving it a question of fact in each case that might arise as to whether the food was adulterated.
>
> We have, of course, as you know, informally announced certain tolerances for arsenic, fluorine and lead existing in

This Court also read the FDCA in that manner in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958). There, the Court examined the food adulteration provisions of the FDCA at issue in this case, Sections 402(a)(1) and 406(a) of the Act, 21 U.S.C. (1952 ed.) 342(a)(1) and 346(a), in the context of their relationship to the FDCA's color additive provisions, Sections 402(c) and 406(b), 21 U.S.C. (1952 ed.) 342(c) and 346(b).[15] The Court noted that "§ 406(a) [now 406] of the Act * * * *allows* the Secretary to establish tolerances for poisonous substances added to food where the substance is 'required in the production' of the food or 'cannot be avoided by good manufacturing practice'" (358 U.S. at 165-166 (emphasis added)) and found that "the provisions *authorizing* the establishment of tolerances apply only to § 402(a)(1) and (2) and do not apply to § 402(c)'s flat prohibition against the use of uncertified colors" (358 U.S. at 166-167 (emphasis added)). See *id.* at 166 ("Section 406(a) * * * provides for the system of tolerances"). Other courts have also concluded that Section 406 authorizes the agency to rely on either informal action levels or formal tolerances to enforce the adulteration provisions of the

spray residues on fresh fruits, these being 0.01 grain of arsenic per pound, 0.002 grain of fluorine per pound, and 0.025 grain of lead per pound. *The new Act* contains practically the same provision as indicated above but, *in addition, authorizes the Secretary to promulgate tolerances in the case of deleterious substances added to food where the addition cannot be avoided by good manufacturing practices or where such substance is required in the production of the food.*

[15] When *Flemming* was decided, Section 406 of the Act consisted of subsection (a) (which includes the current version of Section 406) as well as subsection (b), which provided: "[the FDA] shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors." Subsections (a) and (b) then in effect did share the common phrase "shall promulgate regulations," but subsection (b), unlike subsection (a), was not qualified by the phrase "to such extent as [the FDA] finds necessary for the protection of public health."

FDCA. See *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149, 151 (5th Cir. 1979); see also *Certified Color Industry Committee* v. *Secretary of HEW*, 236 F.2d 866, 868 (2d Cir. 1956); *United States* v. *Anderson Seafoods, Inc.*, 447 F. Supp. 1151, 1153 n.2 (N.D. Fla. 1978), aff'd, 622 F.2d 157 (5th Cir. 1980); *United States* v. *935 Cases, Etc., Tomato Puree*, 65 F. Supp. 503, 505 (N.D. Ohio 1946); cf. *United States* v. *Goodman*, 486 F.2d 847 (7th Cir. 1973). But see *United States* v. *Ewig Bros.*, 502 F.2d 715, 720 (7th Cir. 1974), cert. denied, 420 U.S. 945 (1975) (dictum).[16]

By contrast, the court below ruled that the Commissioner has the nondiscretionary duty to promulgate regulations governing every added substance before food containing the substances treated in Sections 402 and 406, 21 U.S.C. 342 and 346, may be shipped in interstate commerce and that the FDA may not enforce the FDCA by relying upon action levels. The court relied heavily on the dictionary meaning of what it termed "the critical word 'shall'" in the second clause of Section 406 (Pet. App. 6a), which the court construed as requiring the FDA to promulgate tolerances to exempt food containing any quantity of any unavoidable added poisonous or deleterious substance from the scope of that section (*id.* at 6a-7a). In addition, the court concluded that the phrase "to such extent as [the Commissioner] finds necessary for the protection of public health" modifies the participle "limiting," and thus affects the level of the

[16] Moreover, Section 306 of the FDCA, 21 U.S.C. 336, which permits the FDA "to refrain from prosecuting minor violations," has long been read to permit the FDA to employ action levels to implement the adulteration provisions of the Act. See, *e.g.*, *United States* v. *Boston Farm Center, Inc.*, 590 F.2d at 151; *United States* v. *Goodman*, 486 F.2d at 855; *United States* v. *Thriftimart, Inc.*, 429 F.2d 1006, 1011 (9th Cir.), cert. denied, 400 U.S. 926 (1970); *Dean Rubber Manufacturing Co.* v. *United States*, 356 F.2d 161, 164 (8th Cir. 1966); *United States* v. *1500 Cases More or Less, Tomato Paste*, 236 F.2d 208, 211-212 (7th Cir. 1956); *United States* v. *449 Cases, Containing Tomato Paste*, 212 F.2d 567, 572-573 (2d Cir. 1954); *United States* v. *133 Cases of Tomato Paste*, 22 F. Supp. 515, 516 (E.D. Pa. 1938).

tolerances that must be established rather than the FDA's discretion whether to adopt a tolerance at all. *Id.* at 7a. Accordingly, the court of appeals concluded that, in the absence of a formal tolerance, a food is adulterated if it contains any quantity of any substance specified in Section 406. Pet. App. 7a. We submit that the reasons offered by the court of appeals are plainly insufficient to overcome the FDA's settled construction of the Act.

1. *The FDA's Construction Of Section 406 Gives Effect To The Interrelationship Between Sections 402(a)(1) And 406*

Although the court of appeals properly began its analysis of the statute by looking to its plain terms (see *CPSC* v. *GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980)), the court went astray by focusing on the term "shall" in Section 406 to the exclusion of the statute as a whole. This Court has repeatedly explained that, "[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Philbrook* v. *Glodgett*, 421 U.S. 707, 713 (1975) (citation omitted); *Bob Jones University* v. *United States*, 461 U.S. 574, 586 (1983). By fixing exclusively on one possible interpretation of the literal meaning and placement of the term "shall" and failing to consider the relationship between Sections 402(a)(1) and 406, the court of appeals not only misconstrued Section 406, but also rendered Section 402(a)(1) superfluous for added substances, like aflatoxin.

a. *Section 406 Does Not Render Adulterated A Food Containing A Required Or An Unavoidable Added Poisonous Or Deleterious Substance In The Absence Of A Tolerance.* The starting point for analysis of the food adulteration provisions of the FDCA is Section 402, 21 U.S.C. 342, which establishes the general definition of "adulteration." Section 402 covers food containing either an added or an inherent substance. Since aflatoxin is an

added substance, only that portion of Section 402 applicable to added substances is directly relevant in this case.

Food containing an added poisonous or deleterious substance is deemed to be adulterated under Section 402 in two different situations.[17] First, under Section 402(a)(1), the food is adulterated if the substance is present in a sufficient quantity that the food may be injurious to health. 21 U.S.C. 342(a)(1). This section has been part of the federal food regulatory scheme since 1906, and it establishes a general, qualitative standard. Second, under Section 402(a)(2)(A), the food is adulterated if it is "unsafe" within the meaning of Section 406, 21 U.S.C. 346. 21 U.S.C. 342(a)(2)(A). Section 406 establishes a quantitative standard of adulteration.

The first sentence of Section 406 consists of two separate clauses, each of which covers a different situation. Under the opening clause of Section 406, the addition of a poisonous or deleterious substance to a food renders the food unsafe (and thus adulterated) if the substance is not required in the production of the food or is avoidable. The next clause of Section 406 addresses the alternative situation in which the addition of a poisonous or deleterious substance to food is required in food production or is unavoidable. In that circumstance, Section 406 renders a food unsafe if a tolerance is in effect and the food contains the added contaminant in an amount that exceeds the tolerance. Put another way, Section 406 bans the addition to food of a poisonous or deleterious substance when that substance is *not* required in food production or is *not* unavoidable. However, when the addition of a poisonous or deleterious substance to food *is* required in food production or *is* unavoidable, Section 406 does not automatically render unsafe food containing such a substance; only when the amount of that substance exceeds the level fixed by a tolerance is the food deemed to be adulterated.

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[17] Section 402(a)(2)(B) involves raw agricultural commodities containing pesticides, Section 402(a)(2)(C) involves food additives, and Section 402(a)(2)(D) involves new animal drugs. None of these sections is directly relevant to this case.

The first sentence of Section 406, then, does not directly address the circumstance in which a substance is required or unavoidable and a tolerance has *not* been established. However, the second sentence of Section 406 offers guidance as to how the statute operates in that situation. It provides that while a tolerance is in effect, a food containing an added poisonous or deleterious substance that is required in food production or is unavoidable is not deemed to be adulterated under Section 402(a)(1). The clear implication of this sentence is that Section 402(a)(1) *does* apply if no tolerance is in effect. In other words, the existence of a tolerance operates to exempt tainted food from the general adulteration standard found in Section 402(a)(1); in the absence of a tolerance, food is still subject to that section, under which a food is adulterated if it contains an added poisonous or deleterious substance "which may render [the food] injurious to health." The court of appeals therefore misread Section 406 by construing it to require the FDA to set tolerances for required or unavoidable added poisonous or deleterious substances in order to exempt food containing such substances from the automatic adulteration provisions of Sections 406 and 402(a)(2)(A).

Any other conclusion would be inconsistent with this Court's description of the statutory scheme in *Flemming* v. *Florida Citrus Exchange*, *supra*. There, the Court construed Section 406 to carve out specific exemptions from the adulteration provisions in Section 402(a)(1). As the Court explained, "[t]he existence of a tolerance is specifically stated in § 406(a) [currently 406] *only to give sanction to what would otherwise amount to adulteration within the terms of § 402(a)(1)*" (358 U.S. at 166 (emphasis added)). As this Court recognized, when no tolerance is in effect, Section 406 does not apply to added poisonous or deleterious substances that can be the subject of a tolerance; Section 402(a)(1) governs instead.

The court of appeals in essence read Section 406 as if it provides that food containing a required or unavoidable added contaminant is adulterated "unless" a tolerance is in effect. However, Section 406 does not contain that term, even though Congress knows how to draft a statute in that manner. Sections 408(a), 409(a), and 706(a) of the FDCA provide that pesticides, color additives, and food additives are deemed to be unsafe for purposes of Section 402(a)(1) "unless" there is a tolerance or exemption already in effect. See 21 U.S.C. 346(a) (pesticides); 348(a) (food additives); 376(a) (color additives). That difference cannot be attributed to mere legislative oversight; on the contrary, where "'Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion'" (*Russello* v. *United States*, 464 U.S. 16, 23 (1983) (citation omitted)). The court of appeals thus erred by failing to recognize that, in the absence of a tolerance, Section 406 does not render adulterated food containing required or unavoidable added contaminants.

b. *The FDA's Interpretation of Section 406 Gives Effect To The Role Played By Section 402(a)(1) In The Overall Regulatory Scheme.* It is a cardinal rule of statutory interpretation that a statute should be construed so as to give effect to all of its provisions. See, *e.g.*, *Dickerson* v. *New Banner Institute, Inc.*, 460 U.S. 103, 118 (1983); *American Textile Manufacturers Institute, Inc.* v. *Donovan*, 452 U.S. 490, 513 (1981). Here, the FDA's construction satisfies this precept, while the court of appeals' interpretation makes Section 402(a)(1) superfluous for "added" substances like aflatoxin, even though Section 402(a)(1) was expressly designed to play a role in their regulation.[18]

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[18] Section 402(a)(1) states, in part, that "*in case the substance is not an added substance* such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health" (emphasis added). This clause demonstrates that Section 402(a)(1) was meant to govern both added and inherent substances.

Under Section 406, the addition of a poisonous or deleterious substance automatically renders a food "unsafe" (and thus "adulterated" under Section 402(a)(2)(A)) if the added substance is not required in the production of food or can practicably be avoided. Therefore, it is undisputed that Section 402(a)(1) is not needed to regulate those substances. This obviously leaves only added substances that are required or unavoidable. As previously noted, the FDA's view is that it may regulate such added substances either by issuing action levels and bringing suit in appropriate cases under Section 402(a)(1) (in which case the FDA must prove in court that the added substance may render the food "injurious to health") or by promulgating regulations establishing tolerances under Section 406 (in which case any food exceeding those tolerances is automatically deemed to be unsafe and adulterated under Section 402(a)(2)(A)). See *Ciba Corp.* v. *Weinberger*, 412 U.S. 640, 643-644 (1973) (agencies may regulate by formal rulemaking or case-by-case adjudication); *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974) (same); *SEC* v. *Chenery Corp.*, 332 U.S. 194, 201-203 (1947) (same). The agency's interpretation assigns an important role to both Section 402(a)(1) and Section 402(a)(2)(A).

Under the court of appeals' construction, however, the FDA must issue regulations establishing formal tolerances for all required or unavoidable added contaminants. Once these tolerances are in effect, Section 402(a)(1) has no role to play: If a food is "unsafe" under Section 402(a)(2)(A) by virtue of a formal tolerance issued under Section 406, the FDA would have no need to proceed under Section 402(a)(1), which requires proof in court of a reasonable possibility of injury to health; on the other hand, if a food is deemed to be "safe" under such a tolerance, Section 406 expressly provides that the food "shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated" under Section 402(a)(1).

Furthermore, under the court of appeals' interpretation, if a tolerance is *not* in effect, a food is "unsafe" under Section 406 and thus adulterated under Section 402(a)(2)(A), once again leaving Section 402(a)(1) with no role to play. The court's construction of Section 406—rendering adulterated all food containing any required of unavoidable added contaminant, in the absence of a tolerance—thus would effectively eliminate from the FDCA the basic safety standard established by Section 402(a)(1) for all added substances.

Nor can the decision below be defended, as respondents suggest (Br. in Opp. 10), on the ground that Section 402(a)(1) will govern added substances whenever a new added contaminant is discovered until a tolerance is adopted. When Section 406 was enacted in 1938, the FDCA did not provide that Section 402(a)(1) would serve a transitional role until tolerances could be promulgated, although Congress has enacted other interim measures to serve that purpose. See, *e.g.*, the Color Additive Amendments of 1960, Pub. L. No. 86-618, § 203, 74 Stat. 404-407 (authorizing provisional listing of color additives). Moreover, respondents have identified nothing in the statute that would allow enforcement of the Act on a case-by-case basis, using action levels for newly discovered contaminants but not for long-recognized contaminants. And because Section 402(a)(1) does not set any transitional period, courts would be forced to engage in a standardless line-drawing exercise in order to determine when Section 402(a)(1) suddenly became ineffective and Section 402(a)(2)(A) came into play. There is no evidence indicating that Congress intended the FDCA to operate in this peculiar way. If the practical necessities of protecting the public health are an important consideration in the construction of the FDCA, as respondents appear to concede (Br. in Opp. 10), these matters are best left to the expert agency that Congress has entrusted with this responsibility.

2. *The FDA's Construction Of Section 406 Is Consistent With The Role That Provision Plays In The Enforcement Process*

As we have shown, the structure of 21 U.S.C. 342(a)(1) and 346 supports the agency's construction of the statute. Beyond that, the legislative background to the FDCA confirms that the agency's position is fully consistent with the role that Section 406 was meant to play in the enforcement process. Two laws are significant here: the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 *et seq.*, the first comprehensive federal food safety legislation, and the Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, which was the product of several years of intensive legislative study as both Congress and the FDA considered several different proposals to amend the 1906 Act. See generally C. Dunn, *Federal Food, Drug, and Cosmetic Act* (1938); Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 Law & Contemp. Probs. 2 (1939).[19] The background to Section 406, as reflected in these two statutes, reveals that the court of appeals misconstrued the purpose and effect of this section.

a. *The Federal Food and Drugs Act of 1906.* Section 7 of the 1906 Act stated that a food was adulterated if it contained "any added poisonous or other added deleterious ingredient which may render such article injurious to health." § 7 ¶ Fifth, 34 Stat. 770 (codified at 21 U.S.C. (1928 ed.) 8 ¶ "Food"). Within a decade of its enactment, this Court construed Section 7 to reach foods containing such an added substance if the food, "by any possibility," may injure the health of any consumer, "the strong and the weak, the old and the young, the well and the sick." *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, 411 (1914).

[19] Those portions of the legislative history pertinent to Sections 402(a)(1) and 406 are summarized in the appendix to the amicus curiae brief of the National Food Processors Association (at 1a-5a).

So construed, the 1906 Act provided a valuable instrument for protecting the public health. Nonetheless, the FDA concluded that additional enforcement powers would strengthen its hand in two ways. First, in an enforcement proceeding under the 1906 Act each food had to be considered by itself, and exposure to small amounts of the same poisonous or deleterious substance found in a variety of common foods in the diet could not be taken into account in a single proceeding.[20] In addition, unlike today, when federal agencies are often empowered to adopt regulations having the force and effect of law (see *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 295-298 (1979)), the Federal Food and Drugs Act of 1906 did not authorize the Department of Agriculture, the agency then responsible for enforcing that Act, to issue legislative rules defining categories of forbidden substances. The FDA had adopted informal standards for a number of added substances, such as pesticides.[21] But the FDA was required to prove in court on a case-by-case basis that a particular food was adulterated (see *United States* v. *Washington Dehydrated Food Co.*, 89 F.2d 606 (8th Cir. 1937)), a process that the agency

[20] See *Foods, Drugs, and Cosmetics: Hearings on H.R. 6906 et al. Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong., 1st Sess. 60 (1935) (Walter Campbell, Chief of FDA) [hereinafter cited as *1935 H.R. 6906 Hearings*]; *Foods, Drugs, and Cosmetics: Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 596 (1934) (Walter Campbell) [hereinafter cited as *1934 S. 2800 Hearings*]; *Foods, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 19, 24 (1933) (Walter Campbell) [hereinafter cited as *1933 S. 1944 Hearings*].

[21] See, *e.g.*, *1933 S. 1944 Hearings* 22, 28 (Walter Campbell); Notice to Growers and Shippers of Fruits, Dep't of Agriculture (Apr. 2, 1933), *reprinted in 1933 S. 1944 Hearings* 219-220; Notice to Growers and Shippers of Fruits, Dep't of Agriculture (June 20, 1933), *reprinted in 1933 S. 1944 Hearings* 220; Notice to Growers and Shippers of Fruits, Dep't of Agriculture (Dec. 11, 1933), *reprinted in 1933 S. 1944 Hearings* 220; Cavers, *supra*, 6 Law & Contemp. Probs. at 2, 15; *Developments in the Law—The Federal Food, Drug, and Cosmetic Act*, 67 Harv. L. Rev. 632, 642 n.73 (1954).

had to repeat for each new substance and party. Accordingly, when Congress began its consideration of a successor to the 1906 Act, the FDA sought to add to its enforcement power by persuading Congress to grant the agency the discretionary authority to adopt legislative rules applicable to broad classes of contaminants.[22]

b. *The Federal Food, Drug, and Cosmetic Act of 1938.* The FDCA originated in the 73d Congress when the FDA, which drafted the original version of the Act,[23] submitted a bill (S. 1944, 73d Cong., 1st Sess. (1933)) to replace the 1906 Act. Section 10(a) of that proposal, according to Walter Campbell, Chief of the FDA, granted the agency quasi-legislative authority to establish tolerances setting precise levels of forbidden contamination.[24] This section—which FDA Chief Campbell called "an extremely important, in fact, one of the most important provisions of this bill" (*1933 S. 1944 Hearings* 18)—was intended to augment the agency's authority under the existing Act and *Lexington Mill* by empowering the FDA to make factual findings that took into account the range of poisons found in the diet and by allowing the agency to obviate the case-by-case adjudication then required to prove adulteration.[25] The bill submitted by the agency thus clearly provided an additional enforcement tool, not a substitute for its existing authority.

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[22] *1935 H.R. 6906 Hearings* 60 (Walter Campbell); *1934 S. 2800 Hearings* 596 (same); *1933 S. 1944 Hearings* 21, 80 (same).

[23] See *1934 S. 2800 Hearings* 572 (Walter Campbell).

[24] *1933 S. 1944 Hearings* 19 (Walter Campbell) ("[u]nder the terms of this bill the Secretary will be permitted to establish tolerances"); *id.* at 21 (same) ("[w]e are proposing here, in this and other sections of the act, to have authority conferred upon administrative officers to make certain findings of fact. * * * If this section of the bill were to be enacted there could be by executive action the establishment of legal tolerances for added deleterious ingredients"); *id.* at 22 (same) (noting that the public and business is benefitted if there is "some provision * * * for an administrative agency to be empowered on a fact finding basis to give expression to legislative intent").

[25] *1933 S. 1944 Hearings* 18-24, 28, 80-81 (Walter Campbell).

Although the court of appeals found that the verb "shall" in the current version of Section 406 of the FDCA was "critical" to a "common-sense" understanding of the meaning of this provision (Pet. App. 6a), neither the FDA nor Congress attributed any significance to this term; in fact, both the FDA and Congress used the verbs "shall" and "is authorized to" interchangeably. The bill drafted by the FDA used the verb "shall," yet the agency interpreted that bill as authorizing, not requiring, the agency to promulgate tolerances.[26] Senator Copeland, the sponsor of the bill drafted by the agency, stated that the proposal authorized the FDA to adopt tolerances.[27] The FDA consistently took the position during the congressional hearings on the various bills that the agency should be authorized, not required, to issue tolerances.[28] Some of the bills that Congress considered,

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[26] See S. 1944, 73d Cong., 1st Sess. § 10(a) (1933); page 28 note 24, *supra*; see also Annual Report of the Food and Drug Administration (1933), *reprinted at* C. Dunn, *supra*, at 25, 28.

[27] See 77 Cong. Rec. 5722 (1933) (Sen. Copeland) ("Memorandum on the Bill for Revising the Food and Drugs Act, Indicating Differences Between Bill and Present Law"); C. Dunn, *supra*, at 34.

[28] See *1933 S. 1944 Hearings* 19-21, 24, 80 (Walter Campbell); *id.* at 12 (Secretary of Agriculture Wallace) ("[t]he prohibition of added poisons in foods or the establishment of tolerances therefor is provided for"); *1934 S. 2800 Hearings* 596 (Walter Campbell); *Foods, Drugs, and Cosmetics: Hearings on S. 5 Before a Subcomm. of the Senate Comm. on Commerce*, 74th Cong., 1st Sess. 358 (1935) (Walter Campbell) [hereinafter cited as *1934 S. 5 Hearings*]; *1935 H.R. 6906 Hearings* 60, 96 (same). Other parties viewed these proposals in the same way. See *1933 S. 1944 Hearings* 108 (Dr. James Beal, National Drug Trade Conf.) ("Section 10 authorizes the Secretary to determine what added substances in food * * * 'is or may be injurious to health', and either to prohibit the use of such substances or to limit the amount which may be present."); *id.* at 374 (Statement Covering Senate Bill 1944, Kentucky State Board of Health (Dec. 1933)) ("[t]he proposed legislation authorizes the Secretary of Agriculture to establish, upon expert advice, safe tolerances for added poisons in food"); *id.* at 478 (Statement of California Fruit Exchange) (criticizing S. 1944 on the ground that it vests in the Secretary "complete authority to establish * * * tolerances").

such as the version drafted by the FDA, used the verb "shall" in connection with the provision that was ultimately to become Section 406 of the FDCA;[29] other bills used the term "is authorized to."[30] Nonetheless, each of the committee reports explaining these antecedents to Section 406, including the bill eventually enacted as that law, stated that it authorized the FDA to promulgate tolerances.[31]

Throughout the lengthy hearings on the Act, no one proposed that the term "shall" should be inserted into the Act to require the FDA to promulgate tolerances, no one argued that the case-by-case method of proving

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[29] See, *e.g.*, S. 1944, 73d Cong., 1st Sess. § 10(a) (1933); C. Dunn, *supra*, at 43; S. 5, 75th Cong., 3d Sess. § 10(a) (1938); Br. in Opp. 8-9. However, FDA Chief Walter Campbell, who was involved in the drafting of S. 1944, did not construe this term as requiring the FDA to establish tolerances. See *1933 S. 1944 Hearings* 13-28, 58-82. Moreover, following the 1933 Hearings on S. 1944, Senator Copeland, the sponsor of that bill, submitted a revised bill (S. 2000, 73d Cong., 2d Sess. (1933)), that substituted the term "is hereby authorized to" in place of the verb "shall" in Section 10(a) of S. 1944 without saying that he intended to change the substance of the bill. See *1933 S. 1944 Hearings* 493-494, 498. No one who testified on S. 1944 during the hearings stated that the term "shall" imposed a mandatory duty on the FDA to adopt tolerances. S. 5, 75th Cong., 3d Sess. (1938), also contained the term "shall," but no one in the House, where this substitution was made, maintained that this term imposed a mandatory duty on the FDA to promulgate tolerances. See pages 32-33, *infra*.

[30] See, *e.g.*, S. 2000, 73d Cong., 2d Sess. § 10(a) (1934); S. 2800, 73d Cong., 2d Sess. § 12(a) (1934); H.R. 8316, 73d Cong., 2d Sess. § 10(a) (1934); S. 5, 74th Cong., 1st & 2d Sess. § 304(a) (1935); S. 5, 75th Cong., 1st Sess. § 15(a) (1937); C. Dunn, *supra*, at 58, 78, 195, 646.

[31] See S. Rep. 493, 73d Cong., 2d Sess. 4 (1934) (accompanying S. 2800); S. Rep. 361, 74th Cong., 1st Sess. 6 (1935) (accompanying S. 5); S. Rep. 646, 74th Cong., 1st Sess. 3 (1935) (accompanying S. 5); H.R. Rep. 2139, 75th Cong., 3d Sess. 6 (1939) (accompanying S. 5); C. Dunn, *supra*, at 125, 249, 536, 554-555, 667, 820; see also 78 Cong. Rec. 8956 (1934) (Sen. Copeland). The bill (S. 5, 75th Cong., 3d Sess. (1938)) reported in H.R. Rep. 2139, *supra*, was the one ultimately adopted by Congress.

adulteration under *Lexington Mill* should be jettisoned in favor of exclusive reliance upon tolerances, and no one criticized the FDA for jeopardizing the public health by refusing to initiate enforcement proceedings. Rather, the controversy generated by the tolerance-setting features in these legislative proposals stemmed from the procedures by which the FDA would set tolerances, as well as the limited scope of judicial review available to a party seeking to have a tolerance set aside.

The apple industry, which used pesticides to control insect infestation, opposed the FDA's proposal to adopt tolerances for foodstuffs largely on procedural grounds. It complained that a tolerance could be set without the adversarial hearings required by the 1906 Act before a food could be deemed adulterated, and that judicial review was limited to the question whether a tolerance was arbitrary and supported by substantial evidence. Given the abbreviated administrative procedures necessary to set a tolerance,[32] the fact that a tolerance only required the government to prove that a specific level of contamination had been exceeded, and the narrow scope of judicial review, the apple industry claimed that the proposed tolerance provisions would radically alter the nature of

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[32] The original bill submitted by the FDA simply authorized the agency to promulgate tolerances and did not require the agency to follow any particular procedure in so doing. See Sections 10(a) and 23(a) of S. 1944, 73d Cong., 1st Sess. (1933), *reprinted at 1933 S. 1944 Hearings* 5, 10. More elaborate administrative procedures were devised during the course of the hearings in response to criticisms such as those voiced by the apple industry. See 78 Cong. Rec. 2728 (1934) (Sen. Copeland); *id.* at 4567 (same); *id.* at 8956 (same); Fuchs, *The Formulation and Review of Regulations Under the Food, Drug, and Cosmetic Act*, 6 Law & Contemp. Probs. 43, 46-48 (1939). For instance, in the bill that ultimately became the FDCA, the version passed by the Senate (and adopted by the House in a revised form) created a five member Committee on Public Health to serve in a consultative fashion and provided for a limited type of administrative hearing before a tolerance could be promulgated. See Sections 701-703 of S. 5, 75th Cong., 3d Sess. (1938), *reprinted at 1935 H.R. 6906 Hearings* 36-37.

criminal prosecutions for adulteration.[33] The industry's fear was that the substantive tolerance-setting provisions would shift to the defendant the burden of proof on the issue whether a food was adulterated, while the procedural aspects of these provisions (*i.e.*, dealing with the administrative issuance of a tolerance and subsequent judicial review) would emasculate the defendant's ability to prove that the agency's judgment was wrong. Authorizing the FDA to set tolerances vested undue power in its hands, the industry argued, which could be exercised in an arbitrary manner.

In response, the House of Representatives amended the Senate bill (S. 5, 75th Cong., 3d Sess. (1938)) to accommodate the concerns of the apple industry while still s' ngthening the FDA's hand. The House imposed elab- te administrative requirements before a tolerance could b. issued and rewrote the judicial review features of the bill, §§ 701-703, in order to subject a tolerance to exacting administrative and judicial scrutiny before it could become effective.[34] However, the House bill still empow-

[33] See, *e.g.*, *1933 S. 1944 Hearings* 204-210 (Samuel Fraser, Int'l Apple Ass'n); *id.* at 210-220 (Brief of Int'l Apple Ass'n); *id.* at 270 ("Written Analysis of Copeland Bill," submitted by Donald Burke); *id.* at 298-299, 301 (John Hall, Flavoring Extract Mfrs. Ass'n); *id.* at 428-429 (J.W. Herbert, Pacific Northwest Fruit & Vegetable Industry); *id.* at 478 (Prepared Statement of Californ'a Fruit Exchange); *1934 S. 2800 Hearings* 417-452 (Samuel Fraser); *id.* at 220- (Prepared Statement of Flavoring Extract Mfrs.); *1935 S. 5 Hearings* 254-276 (Samuel Fraser); *1935 H.R. 6906 Hearings* 323-336 (R.G. Phillips, Int'l Apple Ass'n); *id.* at 441-443 (Rep. Buck).

[34] H.R. Rep. 2139, 75th Cong., 3d Sess. 9-12 (1938) (describing revisions); *id.* Pt. 2, at 1-4 (Minority Views); *id.* at 3-4 (letter from Secretary of Agriculture Wallace to Rep. Mapes criticizing the review process); 83 Cong. Rec. 7772 (1938) (Rep. Robertson); *id.* at 7775-7776 (Rep. Lea); *id.* at 7783 (Rep. Leavy); *id.* at 7893 (Rep. Robertson); *id.* at 7894 (Rep. Voorhis); *id.* at 7894-7895 (Rep. Leavy); see generally *id.* at 7891-7898 (debate over proposed amendment to judicial review provisions of the FDCA, Sections 701-703 of S. 5, *supra*); Cavers, *supra*, 6 Law & Contemp. Probs. at 20-21; see pages 6-7, *supra* (describing regulatory and judicial review procedures). Some members of the House, which imposed

ered the FDA to issue tolerances. Although the House substituted the verb "shall" for the term "is authorized to" in Section 406(a) of the Senate bill, which granted the FDA the authority to set tolerances, the House did not modify the substance of that section. The House Report described Section 406(a) as authorizing, not requiring, the agency to issue tolerances. See H.R. Rep. 2139, *supra*, at 6 (emphasis added): "This subsection first prohibits the unnecessary addition of poisons. Where such additions are necessary, the establishment of tolerances is *authorized*, based upon the practical necessities for the use of poisonous substances." Moreover, both supporters and opponents of the elaborate administrative and judicial procedures in Sections 701-703 of S. 5, *supra*, agreed that, in regard to Section 406(a), "[t]his bill provides that the Secretary of Agriculture shall have the *authority* after proper hearing to prescribe the extent of spray residue that shall be permissible" (83 Cong. Rec. 7774 (1938) (Rep. Lea) (emphasis added)), and that, "[i]f enacted, this bill would give [the FDA] the *right* after proper hearings to adopt regulations prescribing limits [on pesticide residues]" (*ibid.* (emphasis added)).[35]

In sum, as one contemporary observer noted, "[t]he section defining the Secretary's powers [under Section 406(a)] was constantly revised during the evolution of the measure, but in the end did not greatly differ from

these requirements, stated that they believed these procedures were required by this Court's then-recent decision in *United States* v. *Morgan*, 304 U.S. 1 (1938). See 83 Cong. Rec. 9096, 9098 (1938) (Rep. Lea).

[35] See also 83 Cong. Rec. 7774 (1938) (colloquy between Reps. Sirovich and Lea); *id.* at 7775 (Rep. Lea) ("[i]n this bill we give a broad extension of authority to the Secretary of Agriculture, and in that respect it is one of the broadest bills ever passed by this Congress in ordinary peacetimes"); *id.* at 7784 (Rep. Coffee) ("[t]here is nothing radical or revolutionary about the sections in S.5, which authorize the Secretary of Agriculture to issue a regulation concerning * * * the amount of lead and arsenic which will be permitted on apples shipped in interstate commerce"); *id.* at 9097 (Rep. Lea) ("regulations may be established under this bill"); *id.* at 9100 (Rep. Reece).

that in S. 1944 [the original bill drafted by the FDA]. The major battle arising from this provision was fought on the issue of judicial review * * *." Cavers, *supra*, 6 Law & Contemp. Probs. at 27.

c. *The Effect Of Section 406.* The foregoing discussion demonstrates that the court of appeals misapprehended the import of Sections 402(a)(1) and 406 of the FDCA. As noted, the court of appeals' decision is bottomed in part on its belief that, in the absence of a tolerance, the presence in food of any amount of a required or an unavoidable added poisonous or deleterious substance violates the law, even if the level of that substance in food cannot pose any danger to human health. However, the FDCA has never incorporated that concept of adulteration. This Court squarely rejected that proposition in *Lexington Mill* in construing the predecessor 1906 Act, ruling that an added poisonous or deleterious substance must present a reasonable possibility of injury to the public health before the Act comes into play. See 232 U.S. at 410-411; page 26, *supra*. In the FDCA, Congress retained the prohibition in Section 7 of the 1906 Act, interpreted in *Lexington Mill*, forbidding any "added substance" in food that is poisonous or deleterious and that "may render it injurious to health" (§ 402(a)(1), 21 U.S.C. 342(a)(1)), thereby making clear that it intended to retain the substance of the 1906 Act as that law had been construed by this Court. S. Rep. 493, 73d Cong., 2d Sess. 3 (1934); S. Rep. 361, 74th Cong., 1st Sess. 6 (1935); cf. *Lorillard* v. *Pons*, 434 U.S. 575, 580-581 (1978).[36] The Court recognized in *Flemming* v.

[36] Walter Campbell made this precise point when he testified before Congress in 1934. *1934 S. 2800 Hearings* 530. In his words, the language in the pending legislation (that became the FDCA) (*ibid.*):

> is the language of the present law. That language has been considered in litigation which was carried to the Supreme Court, and has been very exhaustively discussed by that Court.
>
> Now, one of the concerns that we have is, first, the most extensive and most effective protections to the public that can be made. Unquestionably the use of the subjunctive provides that. And, second, to preserve the use of language which has already been considered by the Supreme Court.

Florida Citrus Exchange, *supra*, that the interpretation of "adulteration" adopted in *Lexington Mill* was carried forward into the current version of the FDCA, stating that "[t]he language involved in *Lexington Mill* survived generally in the Act's broadest and most general test of food adulteration, § 402(a)(1)." 358 U.S. at 161.

The court of appeals also erred by construing Section 406 as imposing a mandatory duty on the FDA to promulgate tolerances. The legislative history of Section 406 shows that it was designed to arm the FDA with the power to establish tolerances for the variety of foods in which a common poison was required or unavoidable so that the agency could employ an *additional* enforcement weapon against the interstate shipment of adulterated food. The FDA drafted the original version of this section to obtain discretionary authority to promulgate tolerances; Congress used the terms "shall" and "is authorized to" interchangeably when considering the FDCA; and no one challenged that interpretation of these bills. The sole opposition to the tolerance-setting provisions centered on the concern that the FDA would adopt tolerances too readily, not that the agency would fail to issue such regulations. In sum, by reading Section 406 as requiring the FDA to promulgate tolerances in order to exempt a food containing a required or unavoidable added contaminant from being adulterated, the court of appeals stood Section 406 on its head.[37]

[37] Respondents argue (Br. in Opp. 10) that the FDA's construction of the FDCA makes Section 406 superfluous, on the ground that Section 701 authorizes the agency to promulgate regulations to enforce the Act and thus presumably would empower the FDA to establish tolerances in the absence of Section 406. But Section 406 does far more than simply authorize the FDA to establish tolerances; it also provides that a food is not adulterated under Section 402(a)(1) if a tolerance is in effect, even if the FDA could prove in court that the food was potentially harmful. Furthermore, the legislative history of the FDCA shows that Section 406, not Section 701, was designed to provide the substantive standard by which the FDA was empowered to issue tolerances.

It is, in addition, extremely significant that the FDA did not contemporaneously interpret the bill adopted by the House as requiring the agency to set tolerances. The agency did not object to the House amendment to S. 5 on that ground (see H.R. Rep. 2139, *supra*, Pt. 2, at 3-4 (Minority Report) (reprinting letter from Secretary of Agriculture Wallace to Rep. Mapes criticizing the amendments made by the House Committee)); nor did the FDA immediately promulgate tolerances to exempt contaminated food from the scope of the newly-enacted Section 406, which would have been the obvious and necessary response to Congress's imposition on the FDA of the duty to do so. Moreover, if the court of appeals' construction of Section 406 were correct, then the members of the apple industry, who had opposed the grant of an unreviewable tolerance-setting authority to the FDA, would have become outlaws on the day the FDCA went into effect, since no tolerances had yet been promulgated permitting them to use pesticides. Finally, to our knowledge, no member of Congress ever criticized the FDA for failing to undertake the duty that the court of appeals found sprang into being once the FDCA became effective. That is powerful evidence that Congress never imposed any such duty in the first place.

B. The FDA's Longstanding Construction Of The FDCA Is Entitled To Substantial Deference

The structure, purpose, and legislative background of the FDCA thus provide substantial support for the agency's construction of Section 406. Beyond that, a variety of factors at work here present a powerful case for deference to the FDA. The FDA played an important role in drafting the statute (see *Miller* v. *Youakim*, 440 U.S. 125, 144 (1979)); the interpretation at issue involved a contemporaneous construction of the statutory language (see *Udall* v. *Tallman*, 380 U.S. 1, 16 (1965)); the FDA has consistently adhered to that construction for nearly 50 years (see *Zenith Radio Corp.* v. *United States*, 437 U.S. 443, 450 (1978)); Congress has never expressed its

dissatisfaction with the FDA's regulatory approach despite making revisions to related provisions of the FDCA (see *United States* v. *Rutherford*, 442 U.S. 544, 554 n.10 (1979)); in fact, Congress expressly noted and relied upon the agency's views when enacting those modifications (see *Riverside Bayview Homes, Inc.*, slip op. 13-15); and, of course, Sections 402 and 406 are central portions of a complex regulatory scheme that the FDA is charged with administering (see *Central Lincoln*, slip op. 8).

1. *The FDA Has Followed An Unwavering Construction Of 21 U.S.C. 342 And 346 Since The Inception Of The FDCA Nearly A Half-Century Ago*

For almost 50 years, the Secretary has consistently and publicly interpreted the FDCA as providing the FDA with the discretion to select between informally adopted action levels or formal tolerances to prevent the distribution of adulterated foods in interstate commerce. The FDA took this position from the outset, stating that Section 406 "authorized" the agency to promulgate tolerances. See *Trade Correspondence* 136 (Mar. 7, 1940), *reprinted in* 1 V. Kleinfield, C. Dunn, & A. Kaplan, *supra*, at 622 (page 17 note 14, *supra*).[38] The agency has also adhered to this position to the present. In 1974, for instance, in proposing regulations to govern the decision when formal tolerances should be promulgated, the agency stated explicitly that, under the Act, "[t]he Commissioner is not required to establish a tolerance for every added poisonous or deleterious substance * * *." 39 Fed. Reg. 42745. Three years later, the FDA issued regulations setting forth guidance as to when the FDA would proceed by formal tolerances rather than by action levels. See 21 C.F.R. 109.6(b) and (c). These regulations are neces-

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[38] See also *Trade Correspondence* 5-A (Nov. 5, 1945), *reprinted in* 1 V. Kleinfield, C. Dunn, & A. Kaplan, *supra*, at 751 (emphasis added) ("a tolerance *may* be fixed by regulation"); *Trade Correspondence* 3-A (Nov. 5, 1945), *reprinted in* 1 V. Kleinfield, C. Dunn, & A. Kaplan, *supra*, at 750 (stating that the FDA would not take action against apples and pears containing not more than 7 milligrams of DDT per kilogram of fruit).

sarily premised on and manifest the agency's belief that it had not been precluded by Congress from selecting between these alternatives. And the decided cases acknowledge that the FDA has relied on action levels in enforcing the food adulteration provisions of the FDCA. See, *e.g.*, *United States* v. *Boston Farm Center, Inc.*, *supra*; *United States* v. *Goodman*, *supra;* pages 18-19, *supra.* The agency's historic and unwavering interpretation of Section 406 is therefore entitled to substantial deference. See *Chevron*, slip op. 5-7; *Rutherford*, 442 U.S. at 553-554.

To be sure, the court of appeals' literal reading of the statute is not irrational. The word "shall," Justice Cardozo once wrote for the Court, "is the language of [a] command" (*Escoe* v. *Zerbst*, 295 U.S. 490, 493 (1935)). But he also made clear that the plain meaning of this term was "not controlling", because the courts must consider "a view of the ends and aims" of the legislation under consideration (*ibid.*). Here, the court of appeals did not deny that the FDA's interpretation of the statutory language was entirely rational and plausible. Nor did the court find that the agency's interpretation of the Act was foreclosed by its legislative history, created internal inconsistencies in the overall structure of the FDCA, produced anomalous results that Congress could not have intended, or created a regulatory loophole threatening the public health. The dictionary meaning of the term "shall" therefore provides no basis for overriding the agency's historic interpretation of a statute that it has been entrusted by Congress to administer, especially in view of the statute's obvious complexity. See *Pattern Makers* v. *NLRB*, No. 83-1894 (June 27, 1985), slip op. 19; *Chemical Manufacturers Ass'n* v. *NRDC*, No. 83-103 (Feb. 27, 1985), slip op. 8. As the Court has remarked, the FDCA must "be treated as a working instrument of government and not merely as a collection of English words." *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943). Since the FDA's construction of Section 406 implements the Act in this manner, the

statute should not be construed to defeat the agency's longstanding interpretation.[39]

2. *Congress Has Endorsed The FDA's Construction Of The FDCA In Amending The Act*

Longevity is not the sole factor militating in favor of the FDA's construction of the FDCA. The FDA's interpretation is entitled to enhanced deference because Congress specifically noted the agency's position while considering revisions of the FDCA and did nothing to alter that administrative practice. See, *e.g.*, *Haig* v. *Agee*, 453 U.S. 280, 297-298 (1981); *Chemehuevi Tribe of Indians* v. *FPC*, 420 U.S. 395, 410 (1975); *NLRB* v. *Gullett Gin Co.*, 340 U.S. 361, 366 (1951). Indeed, the legislative history of 21 U.S.C. 346a, which was adopted to modify Sections 402(a)(1) and 406, shows that Congress approved and relied upon the agency's position.

Under the FDCA, pesticides in food were originally governed by Section 406, 21 U.S.C. 346. However, in 1954 Congress enacted a new statute, 21 U.S.C. 346a, to regulate the presence of pesticide residues in raw agricultural commodities.[40] During the congressional hearings

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[39] The court of appeals also found that its construction of Section 406 was compelled by the structure of that provision. Pet. App. 7a. But even if the court believed that its own reading of the statute corresponded with the most refined rules of grammar, that too is an insufficient reason for refusing to defer to the agency's interpretation. Complex regulatory statutes are frequently written in a language that is all their own, and adherence to the strictest grammatical standards is not always a reliable way to divine Congress's intent (see *Flora* v. *United States*, 362 U.S. 145, 150 (1960) ("[t]his Court naturally does not review congressional enactments as a panel of grammarians")). Congress's use and placement of the word "shall" therefore simply marks the beginning of the inquiry, not the end.

[40] Section 346a(b) provides in pertinent part (emphasis added):

> The Administrator [of EPA] *shall promulgate regulations establishing tolerances* with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally

on this legislation, both the Commissioner of Food and Drugs and industry representatives expressly called to Congress's attention the FDA's position on the meaning of Section 406.[41] Thereafter, the agency's construction

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recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, *to the extent necessary to protect the public health.*

[41] The FDA Commissioner, Charles W. Crawford, stated (*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 4277 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. 121 (1953)):

> We have given out so-called informal tolerances on a great many of these things, we have freely given that out and if their schedules bring those spray residues within those informal tolerances there is no basis under the law for us to proceed because if we proceed on the other provision of section 402 [21 U.S.C. 342]—that is 402(a)(1) [21 U.S.C. 342(a)(1)], we have to assume the burden of proving that the quantity of the spray residue present in this particular commodity here in and of itself may injure the health of consumers and we would not give a tentative tolerance at a figure where there was any likelihood of our being able to make a case of that kind.

The National Canners Association wrote to both the House and Senate committees to express its understanding that Section 408 (21 U.S.C. 346a) would apply only to raw agricultural commodities. The Association's letter to the House committee stated (*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 2d Sess. 31 (1954) (emphasis added)):

> It is the understanding of the National Canners Association that after passage of this bill processed foods will be in exactly the same position as before in that *tolerances for pesticide residues with respect to processed foods may be established under section 406* [21 U.S.C. 346] *of the Act*; that in the event the Secretary acts to establish a tolerance for residues on processed foods under section 406 actions for adulteration will be taken under section 402(a)(2) *but if the Secretary has not acted under section 406 any action for adulteration because of excessive pesticide residue in the processed food will still be taken under section 402(a)(1)* [21 U.S.C. 342(a)(1)]. This understanding of the canning industry is, we are advised, shared by Dr. Miller [*i.e.*, Representative Miller, the sponsor of

not only was expressly noted without objection by both the House and Senate committees, but also appears to have played an important part in their thinking. See H.R. Rep. 1385, 83d Cong., 2d Sess. 2, 3, 6-7 (1954); S. Rep. 1635, 83d Cong., 2d Sess. 2, 3, 6-7 (1954).

For instance, the House Report, in describing the existing law, noted that when an added poisonous or deleterious substance is required in food production or practically unavoidable, "a tolerance *may* be established by the Secretary" (H.R. Rep. 1385, *supra*, at 2 (emphasis added)). The House Report also recognized that the FDA from the outset had adhered to and implemented its position that Section 406 was discretionary, observing that, while the law "authorizing" the issuance of formal tolerances had been in effect for more than 15 years, "[d]uring all that time control has been exercised through unofficial and informal tolerances" (*ibid.*). The House Report continued (*id.* at 2-3) that in 1950 "lengthy public hearings," costing nearly $500,000, had been held for the purpose of establishing official tolerances for pesticide residues in fresh fruits and vegetables but that official tolerances still had not been promulgated due to "the cumbersome, time-consuming, and impracticable procedure prescribed by existing law." To overcome these difficulties, the House committee recommended "an improved procedure for establishment of tolerances for pesticide chemicals remaining in or on raw agricultural commodities" (*id.* at 2). And to implement this goal, Section 3 of the Act ultimately adopted (Act of July 22, 1954, ch. 559, 68 Stat. 511 *et seq.*), according to the House Report, "gives to the Secretary * * * the *authority* to establish tolerances" (H.R. Rep. 1385, *supra*, at 8). The

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the House bill], by the FDA, and by all others interested in this legislation.

See also *Residues of Pesticide Chemicals: Hearing on S. 2868 and H.R. 7125 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 83d Cong., 2d Sess. 93 (1954) (NCA letter to the Senate committee chairman to the same effect).

Senate Report made the identical points. See S. Rep. 1635, *supra*, at 2, 3, 6, 8.

Thus, the congressional committees expressly observed that the FDA was relying chiefly on informal rather than formal tolerances, yet they did not suggest that this practice was unlawful or undesirable, and they did nothing to require its abandonment in favor of exclusive reliance on formal rulemaking. On the contrary, both committees sharply criticized the formal statutory procedure set out in the FDCA and crafted a new, simpler, and speedier method for rectifying the problem caused by the breakdown of the formal procedure in the field of pesticide residues on raw agricultural commodities. Beyond that, although the statute Congress adopted provides that "[t]he Administrator shall promulgate regulations establishing tolerances * * * to the extent necessary to protect the public health" (21 U.S.C. 346a(b); see pages 39-40 note 40, *supra*), both the House and Senate Reports expressly described this provision as authorizing, not mandating, the adoption of formal tolerances, much as Congress had done when it adopted Section 406 of the FDCA. See H.R. Rep. 1385, *supra*, at 8; S. Rep. 1635, *supra*, at 2, 3, 6, 8.[42]

[42] Nor is this the only instance in which the FDA brought its construction of Sections 402 and 406 to Congress's attention. In the hearings preceding the adoption of the Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 *et seq.*, the FDA submitted a section-by-section analysis of the bill, stating that Section 102(a) "makes explicit, with regard to color additives, the interpretation of the Supreme Court in *Flemming* * * * that section 406(a) of existing law—which *authorizes* the establishment of tolerances for poisonous or deleterious substances added to food * * * —cannot serve as a basis for allowing the use of coal tar colors." *Color Additives: Hearings on H.R. 7624 and S. 2197 Before the House Comm. on Interstate and Foreign Commerce*, 86th Cong., 2d Sess. 27 (1960) (emphasis added). The House Report on the Act quoted the agency's analysis verbatim. See H.R. Rep. 1761, 86th Cong., 2d Sess. 69 (1960). In the hearings on the Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 *et seq.*, the agency once again informed Congress of its view on the meaning of Section 406. See *Food Additives: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 85th Cong., 2d Sess. 41 (1958) (letter from Secretary of HEW Folsom to Sen. Harris) ("[a]t present, under section 406(a) of the [FDCA], the Secretary is authorized to limit the poisonous or deleterious substances required in the production of food to such extent as he finds it necessary for the protection of public health").

The history of these amendments to the FDCA shows beyond question that Congress endorsed the FDA's interpretation of the statutory provisions at issue. As the Court has made clear, "once an agency's statutory construction has been 'fully brought to the attention of the public and the Congress,' and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned." *Rutherford*, 442 U.S. at 554 n.10. Indeed, here, Congress did more than decline to disturb the FDA's views; it actually incorporated those views into the new statute. Cf. *Riverside Bayview Homes*, slip op. 15; *Bob Jones University*, 461 U.S. at 601-602.

3. *The Court Of Appeals' Ruling Hampers The Effective Enforcement Of The FDCA*

Respondents have not suggested, and the courts below did not find, that the 20 ppb action level set by the FDA for aflatoxin does not adequately protect the public health, that formal tolerances are essential to prevent the interstate shipment of adulterated food, or that the FDA is not satisfactorily enforcing the FDCA. Nor did respondents offer any evidence to support such a claim. In fact, the historical record reveals that the FDA has vigorously enforced Section 402(a)(1) against added contaminants in food.[43]

[43] For a sampling of the FDA's enforcement efforts, see, *e.g.*, *United States* v. *Boston Farm Center, Inc.*, *supra* (FDA obtained an injunction prohibiting the marketing of aflatoxin-contaminated corn); *Seabrook Int'l Foods, Inc.* v. *Harris*, 501 F. Supp. 1086 (D.D.C. 1980), aff'd *sub nom. Continental Seafoods, Inc.* v. *Schweiker*, 674 F.2d 38 (D.C. Cir. 1982) (FDA issued a prohibition against importation of salmonella-contaminated Indian shrimp); *United States* v. *Anderson Seafoods, Inc.*, *supra* (FDA obtained an

The court of appeals no doubt assumed that its construction of the FDCA would contribute to the effective enforcement of the Act. Cf. *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (noting that the FDCA should be liberally construed in order to protect the public health); *Dotterweich*, 320 U.S. at 284 (same).[44] Quite the contrary is true, however. Unless reversed, the court of appeals' decision will have a significant adverse impact on the administration of the Act.

First, and most important, formal tolerances, once set, may retard the FDA's ability to respond quickly to new scientific findings or improvements in manufacturing processes that make it practicable to reduce the level of adulterants. See 21 C.F.R. 509.6(b)(3). Unlike other statutory provisions authorizing the emergency ban of pesticides (see 7 U.S.C. 136d(c)(3)) or drugs (see 21 U.S.C. 355(e)) found to pose an imminent hazard to the public health, the FDCA makes no provision for either

injunction prohibiting the marketing of mercury-contaminated swordfish).

The decided cases, of course, represent only a tiny fraction of the FDA's use of action levels to prevent the distribution of adulterated food in interstate and foreign commerce. Sections 702 and 704 of the FDCA, 21 U.S.C. 372 and 374, authorize the Commissioner to conduct inspections and to take and analyze food samples to determine whether they are adulterated. Each year, in accordance with instructions issued to its field offices, the FDA analyzes approximately 10,000 articles of domestically produced and imported food. The FDA thereafter recommends judicial enforcement actions only if the agency cannot obtain voluntary compliance by the person involved. Litigation therefore is the last step in the FDA's enforcement efforts and is necessary only on rare occasions.

[44] The court of appeals may have made this assumption because of its belief that any amount of aflatoxin "may render [food] injurious to health" under Section 402(a)(1). Pet. App. 4a. However, the only evidence of record on this point shows that food must contain at least 20 ppb aflatoxin in order to present any reasonable possibility of harm. See J.A. 193, 194, 225. Moreover, for certain uses, corn must contain more than 100 ppb aflatoxin before it may become injurious to health. See pages 9-10 note 10, *supra*.

the emergency revocation of a tolerance or the emergency condemnation of food meeting a tolerance. Once a formal tolerance is in effect, a food that does not exceed that tolerance is automatically deemed to be safe and unadulterated under Sections 402(a)(2)(A) and 406, 21 U.S.C. 342(a)(2)(A) and 346. Moreover, Section 406 provides that the food may not then be considered to be adulterated within the meaning of Section 402(a)(1)—even if the government could prove in court that the food may be "injurious to health." Thus, if a formal tolerance is issued and it is later discovered that the limit is too high, foods that satisfy the formal tolerance but that may in fact be unsafe according to the latest scientific studies will still be considered safe and unadulterated under the FDCA until the lengthy process of issuing a new, lower tolerance can be completed.[45]

Second, the court of appeals' reading of the statute would impose a severe administrative burden on the FDA and require the reallocation of scarce resources from activities of far greater utility in protecting the public health. Although the FDA originally expected that the authority to adopt tolerances would prove to be a valuable addition to the agency's enforcement arsenal, the exacting administrative and judicial review process

[45] This point is graphically illustrated by the FDA's experience with formal tolerances for polychlorinated biphenyls (PCBs). Based on newly obtained toxicological data, the FDA in April 1977 proposed to lower the existing tolerance from 5 parts per million (ppm) to 2 ppm for residues of PCBs in fish, shellfish, and several other classes of food. 42 Fed. Reg. 17487. The final rule was promulgated in 1979. 44 Fed. Reg. 38330. At the request of a fishing industry trade association, a hearing was held in May 1981. The FDA issued its decision in March 1982. 47 Fed. Reg. 10079. After the agency invited the submission of other relevant material (*ibid.*), the final decision was issued in May 1984. 49 Fed. Reg. 21514. During all this time, the 5 ppm tolerance remained in effect, thereby exposing consumers to levels of PCBs that the FDA considered potentially harmful. The entire process of lowering the tolerance for PCBs in fish and shellfish took seven years, although a comparable amendment of an action level could have been effected in a relatively brief period.

imposed by Congress in Section 701, 21 U.S.C. 371 largely defeated the agency's hopes. Despite showing some initial promise,[46] the tolerance-setting procedures, the FDA has learned, are often protracted and can seriously hamper the agency's ability to respond quickly to new developments.[47] Congress, too, has found that the formal rule-

[46] For example, in 1944 the FDA's predecessor agency took only four months to adopt a tolerance for fluorine spray residues on apples and pears. 9 Fed. Reg. 4654 (1944) (notice of hearing); *id.* at 9754 (proposed regulation); *id.* at 11836 (final order).

[47] This point is also illustrated by the adoption of formal tolerances for PCBs in paper materials used in packaging foods. In March 1972, the FDA proposed to establish formal tolerances for PCBs in food and paper food-packaging materials. 37 Fed. Reg. 705. In July 1973, the FDA published a final rule based on the proposal. 38 Fed. Reg. 18096. At the request of several paper industry firms a public hearing was granted. 40 Fed. Reg. 11563 (1973). Subsequently, the FDA's Bureau of Foods and the industry parties reached a proposed settlement agreement, which was submitted for the Commissioner's approval in November 1978. After further proceedings, a revised settlement agreement was announced in the *Federal Register* in August 1983. 48 Fed. Reg. 37020. Thus, the promulgation of a formal tolerance—where there was an objection but, by mutual agreement, no full trial-type hearing—took more than a decade to complete.

Respondents suggest (Br. in Opp. 13) that the formal rulemaking requirements of 21 U.S.C. 371(e) are not burdensome for the agency because the FDA can invoke the summary judgment procedures upheld in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973). That procedure may alleviate some of the congestion that is likely to ensue if the court of appeals' judgment is upheld, but it does not fully remedy the problem. FDA summary decisions can be, and have been, set aside by the courts. See, *e.g.*, *Hynson*, 412 U.S. at 622-623; *American Cyanamid Co.* v. *FDA*, 606 F.2d 1307 (D.C. Cir. 1979); *Edison Pharmaceutical Co.* v. *FDA*, 513 F.2d 1063 (D.C. Cir. 1975). Moreover, because the question in a tolerance-setting proceeding is the appropriateness of the level selected by the FDA, which requires the agency to consider the overall economic impact of that level (see 21 C.F.R. 509.6(b)(1); 42 Fed. Reg. 52816 (1977)), there is no reason to assume that objectors would not be able to raise genuine and substantial factual issues, which would prevent the FDA from granting summary judgment. (Indeed, respondent Public Citizen's Health Research Group was recently able to raise such issues in the context of, and to obtain a hearing

making procedures set forth in Section 701(e) are "cumbersome, time-consuming, and impracticable." S. Rep. 1635, *supra*, at 2; H.R. Rep. 1385, *supra*, at 3.

Nonetheless, court of appeals' decision would mandate such proceedings for numerous substances. The FDA currently has 21 action levels for eight added substances that could be regarded as within the scope of Section 406.[48] These substances can contaminate foods such as red meat, fish, milk and dairy products, eggs, corn, and wheat. See J.A. 150, 156, 165, 166, 167. Since a different action level may be necessary for each of several human foods and animal feeds, a given substance can require several action levels. Therefore, a tolerance-setting proceeding under Section 701(e) might likewise include a number of tolerances for each substance, depending on the food or feed involved. The greater the number of foods or feeds considered, the more complicated and time consuming the proceeding would be. The decision below, at the least, would seem to require that each of the FDA's current action levels be replaced by a formal tolerance.[49]

on, the FDA's final rule permanently listing a particular color additive for general use in food and in ingested drugs. See 40 Fed. Reg. 51145-51146 (1973) (notice of hearing).) In any event, there is no reason to assume that the extended litigation that would follow from an affirmance of the court of appeals' judgment would enhance the FDA's current ability to protect the public health, and respondents offered no evidence below that would justify such a conclusion.

[48] The FDA action levels to which Section 406 could now apply are: aflatoxin, cadmium, crotolaria seeds, mercury, nitrosodimethylamine (NDMA), paralytic shellfish toxin, polybrominated biphenyls (PPBs), and PCBs.

[49] Moreover, the logic of the court of appeals' decision is not limited to those substances for which an action level has already been set but rather extends to the whole universe of added, unavoidable poisonous or deleterious substances in food. Many of these substances may occur only in negligible amounts in a multitude of foods for which there is no existing action level; many of these substances, although undetectable using currently-available analytical methods, may be found in a variety of foods as such methods

Of course, the burden of establishing tolerances through the formal rulemaking process is not a sufficient reason for failing to do so if Congress required the FDA to regulate in this manner. But the FDA has found that the establishment of formal tolerances does not protect the public health to any significant degree beyond that afforded by its reliance on informal action levels. The FDA has long viewed the decision whether to establish formal tolerances as largely a question whether doing so will enhance its ability to enforce the food adulteration provisions of the FDCA by obviating the need to prove in court on a case-by-case basis that a certain food may present a danger to the public health by virtue of the particular level of a specific contaminant that it contains. Given the negligible addition to its enforcement power resulting from the establishment of tolerances, and the risk that their adoption might reduce (or, in some cases, eliminate) the flexibility necessary to respond to changed circumstances, the FDA has found that formal tolerances are not currently essential to its regulatory mission. There is *no* evidence that Congress disagrees with FDA's considered view, which represents precisely the type of scientific and policy judgment that Congress commonly entrusts to the administrative agency responsible for enforcing a complex regulatory scheme. See *Heckler* v. *Chaney*, No. 83-1878 (Mar. 20, 1985), slip op. 10; *Chevron*, slip op. 5-7. Construing the FDCA to require the FDA to adopt formal tolerances in these circumstances would hinder rather than promote the Act's purpose of protecting the public health by needlessly diverting the agency's limited resources from matters of more urgent public concern.

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become more sensitive; and many of these substances may yet be undiscovered. Aflatoxin, for example, was not discovered until the early 1960s. J.A. 34. But under the court of appeals' interpretation of Section 406, every one of these substances must be regulated by a formal tolerance, and every proposed modification of a tolerance must go through the same prolonged rulemaking process.

Finally, the reasoning of the court of appeals casts a cloud over the legality of large portions of the nation's food supply. As noted above, the court of appeals was under the mistaken belief that unless a formal tolerance has been issued any food containing an added, unavoidable poisonous or deleterious substance must be considered to be adulterated. Pet. App. 15a. Because many segments of the food supply now contain such substances (albeit in safe amounts), the necessary implication of the court's reasoning is that this food is "adulterated" within the meaning of 21 U.S.C. 342(a)(2)(A) and that persons responsible for growing, processing, or distributing it in interstate commerce are in violation of 21 U.S.C. 331 and are subject to an injunction (see 21 U.S.C. 332), seizure of the food (see 21 U.S.C. 334), or even criminal penalties (see 21 U.S.C. 333). For those potentially affected, it is cold comfort that the government would exercise its enforcement discretion in a fair and reasonable manner. See 21 U.S.C. 336; *Heckler* v. *Chaney*, *supra*. The affected parties ought not to be subjected to that risk in the absence of far clearer evidence than the court of appeals was able to muster that Congress intended the regulatory process to be structured in an entirely different fashion.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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FEBRUARY 1986

APPENDIX

STATUTORY AND REGULATORY PROVISIONS INVOLVED

1. Section 402(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a), provides:

A food shall be deemed to be adulterated—

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and

the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

2. Section 406 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346, provides:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

3. Section 701(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(e), provides:

> (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.
>
> (2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor,

and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

4. 21 C.F.R. 509.6(b)-(c) provides:

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacuring practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account

the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

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No. 85-664

IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE,
PUBLIC CITIZEN and LINDA S. BARDOT,
Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE
DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF RESPONDENTS

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QUESTION PRESENTED

May the Food and Drug Administration set the permissible level for an acknowledged carcinogen in food without permitting any public participation, when the Food, Drug, and Cosmetic Act provides that the agency "shall promulgate regulations limiting the quantity" of such a substance through a formal rulemaking proceeding?

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

No. 85-664

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE,
PUBLIC CITIZEN and LINDA S. BARDOT,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF RESPONDENTS

This case concerns the method used by the Food and Drug Administration ("FDA") to regulate environmental contaminants called "aflatoxins." Although the FDA admits that aflatoxins are a poisonous substance for which there is no safe level, since 1969 it has officially sanctioned the sale of corn and certain other agricultural products containing aflatoxins. Respondents do not challenge the FDA's authority to permit the sale of foods containing unavoidable substances such as aflatoxins. Instead, the issue in this case concerns the legality of the method chosen by the FDA to set the allowable level of aflatoxins and other unavoidable, poisonous substances that enter the food supply.

This case turns on section 406 of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. § 346, which provides that the FDA "shall" issue regulations limiting the permissible levels of substances such as aflatoxins. Section 701(e), 21 U.S.C. §

371(e), in turn lists section 406 as one of the provisions of the Act that is subject to formal rulemaking requirements. However, rather than use these procedures to regulate these substances, the FDA has created a device which it calls "action levels," under which food containing less than the prescribed amount of the substance may be lawfully sold. Although "action levels" have the same legal effect as a regulation issued under section 701(e), the FDA issues them without providing any opportunity for public participation. Because respondents seek the opportunity to present their own evidence and to comment on the evidence relied on by the FDA in setting the permissible levels of aflatoxins, they brought this action to require the FDA to comply with the clear mandate of section 406.

STATUTES INVOLVED

The Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717 (1938), 34 Stat. 770, 21 U.S.C. §§ 301, *et seq.*, provides in pertinent part as follows:

Adulterated Food

Sec. 402 [21 U.S.C. § 342]. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406. . . .

Tolerances for Poisonous Ingredients in Foods

Sec. 406 [21 U.S.C. § 346]. Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

Regulations and Hearings

Sec. 701(e) [21 U.S.C. § 371(e)]. (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested persons, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. . . .

* * * *

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. . . .

STATEMENT

A. Aflatoxins

Aflatoxins are a group of chemically related substances produced by molds that grow on corn and other agricultural products. Sometimes described as "the most potent carcinogen known in laboratory animals,"[1] they have been shown to cause liver tumors in six species of animals, and epidemiological studies conducted in Southeast Asia and Africa indicate that aflatoxins are human carcinogens. J.A. 35-36. While no similar studies have been conducted in the United States, the FDA has consistently treated aflatoxins as "liver carcinogens" with "extreme potency," and on this basis the agency concluded in 1974 that it should "take actions to hold human exposure to aflatoxins in the United States to the lowest level possible." *Id.* The FDA estimated that eliminating aflatoxins in peanuts alone would reduce the lifetime incidence of liver cancers in the United States by 2,200. Merrill & Schewel, *FDA Regulation of Environmental Contaminants of Food*, 66 Va. L. Rev. 1357, 1408 (1980).

Aflatoxin B_1, the most prevalent member of the strain, is many times more potent than most carcinogens regulated by the FDA. For example, when the FDA proposed to ban saccharin, it relied on animal studies which showed that the sweetener caused cancer in approximately 10% of male rats that were fed a diet consisting of up to 5% saccharin. 42 Fed. Reg. 19996, 20000 (1977). By contrast, in an aflatoxins study relied on by the FDA, where the incidence of tumors was approximately 10%, the animal food contained only one part per billion ("ppb") of aflatoxins (J.A.

[1] National Academy of Sciences, *Scientific and Societal Considerations, Food Safety Policy* 3—49 (March 1979).

36); in another study, where rats were fed a diet of 15 ppb of aflatoxins, all 25 animals developed liver tumors. *Id.*

The FDA has endorsed the validity of these animal studies on aflatoxins, and, in a 1974 Federal Register notice, the agency stated that aflatoxins are "among the most potent liver carcinogens known" and that "there is no known acceptable level of intake of aflatoxins." J.A. 35, 46. These studies and the FDA's consistent position that any level of a carcinogen entails a risk to human health demonstrate that there simply is no basis for the FDA's current suggestion (Br. 44 n.44) that food containing aflatoxins is safe as long as it complies with the FDA's action levels.[2] *See also United States v. Boston Farm Center, Inc.*, 590 F.2d 149, 152 (5th Cir. 1979)(FDA expert testified that "there is no known level of exposure [of aflatoxins] which can be considered safe, without risk to people").

B. The Regulation of Aflatoxins

In order to assess the validity of the FDA's use of action levels here, it is necessary to review briefly the relevant statutes and the history of the FDA's regulation of aflatoxins. Section 301(a) of the FDC Act, 21 U.S.C. § 331(a), prohibits the introduction in interstate commerce of any food that is "adulterated." Section 402 of the Act, 21 U.S.C. § 342, contains several definitions of "adulterated" foods, two of which are relevant here. First, under section 402(a)(1), a food is "adulterated" if it contains a "poisonous or deleterious substance which may render it injurious to health." Because the FDA has consistently maintained that there is no known safe level of aflatoxins, foods containing aflatoxins are adulterated under this provision, and thus the FDA may prosecute persons shipping foods containing aflatoxins. Of course, nothing in the statute requires the FDA to initiate

[2] For example, in 1979, when it banned the use of DES as an animal drug, even though the residue in meat was only a few parts per billion, the FDA relied on the opinion of one of its experts that "exposure to any amount of a carcinogen, however small, will contribute to the total carcinogenic effect in the population." 44 Fed. Reg. 54852, 54885 (1979).

enforcement actions against every food that falls within this section, and it may as a matter of prosecutorial discretion choose not to allocate its resources in particular cases after considering such factors as the seriousness of the violation and its competing priorities. *See Heckler v. Chaney*, 105 S. Ct. 1649 (1985).

Second, under section 402(a)(2)(A), a food is also considered to be adulterated "if it bears or contains any added poisonous or deleterious substance . . . which is unsafe within the meaning of section 406." Section 406, 21 U.S.C. § 346, in turn applies to poisonous and deleterious substances that are added to foods. The parties agree that section 406 is applicable to the regulation of aflatoxins because the substance is "added" to foods such as corn by the growth of a mold on the food. However, because aflatoxins are unavoidable in corn, the substance is covered by a specific portion of section 406 which provides that for such substances

> *the Secretary* [of Health and Human Services] *shall promulgate regulations* limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health.

21 U.S.C. § 346 (emphasis supplied).[3] Section 701(e) of the Act provides that these regulations, which are known as "tolerances," shall be issued pursuant to the formal rulemaking requirements of the Act, which include providing interested persons notice, an opportunity to comment, and, if there are any material issues of facts in dispute, an evidentiary hearing. 21 U.S.C. § 371(e). In order to obtain a tolerance, a food producer must demonstrate that the proposed tolerance is the lowest feasible level of the substance and that there will be no threat to the public health. 21 U.S.C. § 346; 21 C.F.R. §§ 109, 509 (1985).

[3] The Secretary has delegated these responsibilities to the Commissioner of the FDA, 21 C.F.R. § 5.10 (1985), and therefore throughout this brief respondents generally refer to the duties under the FDC Act as those of the Commissioner, even though the Act delegates authority only to the Secretary.

Once a tolerance is established, a food which contains a contaminant that exceeds the level of that tolerance is automatically considered "unsafe" within the meaning of section 402(a)(2)(A), and it is thereby prohibited. By the same token, the tolerance operates like a license for food producers, since, as long as the tolerance is in effect, a food containing the contaminant below the level is not unsafe and hence prohibited by section 402(a)(2)(A), nor is it adulterated under the general adulteration standard contained in section 402(a)(1). *See* FDC Act § 406.

The FDA has never issued a tolerance for aflatoxins, but instead the agency limits the public's exposure to them by use of "action levels," a term which does not appear in the FDC Act or the Administrative Procedure Act ("APA"). Action levels are a method of regulation created by the FDA to monitor a variety of substances, including unavoidable contaminants in foods. However, the agency does not issue action levels as regulations, nor does it even publish proposed action levels for comment in the Federal Register. Instead, from time to time it simply announces that it has set new levels.

Despite this significant procedural difference between the issuance of an action level and the adoption of a tolerance, each confers precisely the same benefits on food producers. Thus, provided that the level of a contaminant does not exceed the authorized amount of the action level, food producers receive full protection from FDA enforcement actions. Nevertheless, with one exception, the FDA has not relied on tolerances promulgated under sections 406 and 701(e) to regulate unavoidable poisonous and deleterious substances that are added to foods. 21 C.F.R. §§ 109.30, 509.30 (1985). Instead, it relies almost exclusively on action levels to regulate unavoidable, added substances which it has determined render food adulterated under the FDC Act.

Action levels were initially publicized through press releases or other announcements. J.A. 16. However, in 1974, the FDA proposed regulations that would have governed the use of action levels and tolerances. J.A. 11. As explained in the proposal, the

major difference between the two methods of regulation is that tolerances would have been used "in relatively static circumstances," while action levels would have been used "prior to promulgation of a section 406 tolerance [where the relevant factors to be considered were] rapidly changing." J.A. 21; *see also* J.A. 28-29. In either case, public participation would have been required. However, for action levels, the FDA would have used only the notice and comment procedures in the APA, 5 U.S.C. § 553, whereas it would have issued tolerances in compliance with the formal rulemaking requirements of section 701(e) of the FDC Act. *See* J.A. 27 (action levels to be "established by regulation").

In 1965, the FDA established an action level for aflatoxins at 30 ppb, which was the lowest level of contamination that could be detected under the existing technology. J.A. 37. In 1969, the agency reduced the level to 20 ppb, where it remains 17 years later. When the FDA proposed issuing the action level regulations in 1974, it also proposed a specific tolerance of 15 ppb for aflatoxins in peanuts. J.A. 33. In the Federal Register announcement, the FDA Commissioner explained that he had concluded that continued use of an action level to regulate aflatoxins would only be appropriate "when changes are foreseeable in the near future that might affect the appropriateness of the limitation established." J.A. 47. Because the FDA was "unaware of any new or anticipated developments that would affect the proposed 15 ppb level in the near future," the Commissioner proposed to issue a tolerance for aflatoxins in peanuts. J.A. 47-48. However, the agency never acted on that proposal, and, as a result, aflatoxins in all foods continue to be regulated solely by the 1969 action level of 20 ppb. *See* J.A. 150.

In 1977, the agency issued final regulations regarding its use of action levels and tolerances and published all existing action levels in its Administrative Guidelines Manual. J.A. 53; *see* J.A. 148. In the preamble to the regulations, the FDA responded to a comment that it "must either disclaim any intent to attach the force of law to its action levels, or it must adopt those action levels as tolerances under section 406 of the act and in accord

with the procedures specified in section 701(e) of the act." J.A. 75-76. Not only did the FDA reject this argument, but in its final regulations it deleted the requirement that it comply with the notice and comment procedures of the APA before issuing or amending an action level. J.A. 80. The FDA justified its decision not to comply with the notice and comment requirements of the APA on the ground that action levels would be used only where "industrial practices are improving. . . quickly" or where the data needed to set a tolerance are "scanty" but "are being developed." J.A. 68-70. The FDA stated that in the future it would publish a notice in the Federal Register inviting public comment on new or revised action levels. *See* 21 C.F.R. §§ 109.4(b)(2), 509.4(b)(2) (1985). However, it reserved the right to change its action levels at any time, without allowing the public an opportunity to participate. *Id.* Despite the absence of any procedural protections for the public, action levels have the force of law, as the FDA acknowledged in the Federal Register notice, since food producers are protected so long as the level of contaminants found in food is below the action level. *See also* Pet. App. 1a, 15a (opinion of court of appeals below); J.A. 148 (FDA Action Levels); *United States v. Ewig Brothers Co.*, 502 F.2d 715, 724-25 (7th Cir.), *cert. denied*, 420 U.S. 945 (1974).

The FDA's actual practice with respect to aflatoxins demonstrates how the agency has implemented its regulation providing for public comment. In 1978, the FDA deviated from its long-standing prohibition against "blending" contaminated foods (*see* J.A. 23), by allowing corn with aflatoxins at levels greater than the 20 ppb action level to be blended with less contaminated corn, in order to obtain a mixture within the 20 ppb limit. The decision was contained in a January 31, 1978 letter to a private firm and was not published in the Federal Register until April 4, 1978. J.A. 101, 172; 43 Fed. Reg. 14122. In the fall of 1980, the FDA again permitted blending of corn containing aflatoxins above the action level, and again it waited several months to publish its decision. J.A. 114. And in 1983, while this lawsuit was pending in the district court, the agency once again announced that it had decided to permit blending of corn con-

taminated with high levels of aflatoxin. J.A. 227. Relying on the FDA's regulations, 21 C.F.R. § 109.4(b)(2)(1985), respondents submitted objections to that decision (J.A. 227), but the agency never responded.

C. Proceedings Below

Respondents are two consumer organizations and an individual consumer. Pet. App. 2a. Their complaint, which was filed after the FDA issued its 1980 blending authorization, alleged that the FDA had violated section 406 of the FDC Act by failing to conduct formal rulemaking to set limits for these unavoidable contaminants. J.A. 111. Respondents also contended that, even if section 406 does not require the FDA to use such tolerances, action levels constitute "rules" within the meaning of section 2(c) of the APA, 5 U.S.C. § 551(4), because they are binding on the agency and have a future effect. *Id.* Therefore, respondents argued, at a minimum the FDA is required to publish action levels as proposed rules, provide an opportunity for public comment, and publish the final rule, with a concise statement of its basis and purpose, thirty days before its effective date. 5 U.S.C. §§ 551(5), 553. *See, e.g., Nader v. CAB*, 657 F.2d 453, 456 (D.C. Cir. 1981)("mandatory language, which narrowly circumscribes the Board's discretion to suspend air fares . . . plainly constitutes a substantive rule"); *American Bus Association v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980)("[i]f it appears that a so-called policy statement is in purpose or likely effect one that narrowly limits administrative discretion, it will be taken for what it is—a binding rule of substantive law" to which the rulemaking provisions of the APA apply). Finally, respondents claimed that the FDA's policy of permitting blending of corn contaminated with aflatoxins violated both the FDC Act and the agency's own regulations. J.A. 111.

The district court rejected all three arguments, but the court of appeals reversed on the ground that, under sections 406 and 701(e) of the FDC Act, the FDA is required to follow formal rulemaking requirements in setting permissible levels of aflatoxins. Pet. App. 1a, 21a. Thus, in a unanimous opinion by Judge Starr, the court held that "the intent of Congress is abundantly clear in requiring the formal issuance of tolerances, rather than permitting agency reliance solely on informal action levels." Pet. App. 6a. In reaching its decision, the court relied principally on the plain language of the statute, concluding that the "presence of the critical word 'shall' plainly suggests a directive to the Secretary to establish a tolerance." *Id.* As further support, the court observed that "[t]he interpretation accorded the Act by the FDA flies in the teeth of Congress' clear intent and, under long established principles of administrative law, must therefore be rejected." *Id.* Contrary to the FDA's characterization (Br. 25, 34), the court of appeals did not discuss the legal status of foods containing added, unavoidable contaminants for which no tolerance has been issued, nor did it hold that such foods are *per se* unsafe under section 402(a)(2)(A). Instead, the court merely held that when the FDA officially sanctions an unavoidable contaminant such as aflatoxins, it is obligated to comply with the rulemaking requirements of sections 406 and 701(e).

Since the court of appeals held that the FDA is required to comply with these provisions of the FDC Act, it did not reach respondents' alternative claim that the FDA had also violated the notice and comment requirements of the APA, and it remanded the blending issue to the district court for consideration in light of its decision. Pet. App. 15a-16a. The agency's petition for rehearing and suggestion for rehearing *en banc* was denied, with a notation that no member of the court had requested a vote on whether the case should be reheard by the full court. Pet. App. 18a, 19a.

SUMMARY OF ARGUMENT

The issue in this case can be resolved by the plain meaning of section 406 of the FDC Act. That section establishes a standard for determining whether foods with added but unavoidable contaminants are adulterated, and thereby unlawful. Since, as the parties agree, aflatoxins are added, unavoidable contaminants, section 406 requires that the FDA "*shall* promulgate regulations

limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health" (emphasis supplied). In addition, section 701(e) of the Act directs the FDA to use formal rulemaking procedures when it sets such tolerances under section 406. Thus, it is difficult to imagine how Congress could have drafted statutory language which more clearly expressed its intent that the FDA set the permissible levels for substances such as aflatoxins through a formal rulemaking proceeding.

Instead of following the statutory scheme crafted by Congress, the FDA uses "action levels" to regulate aflatoxins and, with one exception, all other unavoidable contaminants. Even though the FDA issues action levels without affording the public an opportunity to comment, they have the same legal effect as a tolerance since an action level binds the agency from proceeding against food producers whose products contain contaminants below the action level specified by the FDA. However, because the FDC Act explicitly requires the FDA to use formal rulemaking procedures to set tolerances for substances such as aflatoxins, the FDA cannot use action levels for this purpose.

Under the FDA's construction of section 406, the statute would have precisely the same meaning if Congress had used the phrase "is authorized to" in place of the word "shall." In fact, the legislative history demonstrates that Congress considered and rejected that alternative. The bill adopted by the Senate used the words "is authorized to," but the House Committee changed those words to "shall" in section 406 and made similar changes in four other places in the statute. Therefore, the legislative history demonstrates that Congress consciously chose to require the FDA to issue regulations for substances covered by section 406 instead of simply granting the agency the discretion to do so.

The FDA relies on other provisions of the FDC Act to argue that the word "shall" in section 406 really means "may." However, none of the arguments offered to support this construction of the statute is persuasive. The agency's principal contention is that the decision of the court of appeals makes section

402(a)(1) superfluous with respect to added, unavoidable contaminants, since that section prohibits foods that contain added contaminants that "may be injurious to health," but under the decision below all such substances would automatically be covered under section 406. That argument cannot be sustained. Section 402(a)(1) is not superfluous because it is the only provision in the Act which prohibits unavoidable, added substances for which the agency has not yet issued a tolerance under section 406. For example, in the 1960's, when the FDA became aware that aflatoxins are a hazard to the public health, it was obligated to begin the process of establishing a tolerance under section 406. But in the interim, it could have used the general adulteration standard in section 402(a)(1) to proceed against food producers selling food with unhealthy levels of aflatoxins. Thus, between the time that unavoidable contaminants are discovered, and the effective date of the tolerance which the FDA must set under section 406, section 402(a)(1) serves a vital role in the regulation of adulterated products.

Nor is the FDA correct that under the decision below the entire food supply is adulterated under section 402(a)(2)(A). Section 402(a)(2)(A) provides that food is adulterated if it is "unsafe" within 406, and section 406 in turn declares that any food is unsafe if it contains an unavoidable, added poisonous and deleterious substance in excess of the tolerance level promulgated by the FDA. However, because section 402(a)(2)(A) applies only if an existing tolerance has been exceeded, foods containing these contaminants are not in violation of that section if there is no tolerance in effect.

As further support for its argument that the word "shall" in section 406 means "may," the FDA offers a number of policy arguments. Not only are those claims irrelevant to the issue of statutory construction, but they are overstated and ignore policies that explain why Congress chose to use the mandatory language of section 406. For example, the agency has greatly exaggerated the regulatory burdens which the court of appeals' interpretation of the statute would place on it. As it acknowledges, there are only eight substances which fall within

the ambit of section 406 and which the FDA currently regulates with action levels instead of tolerances. Moreover, the agency's ability to issue summary decisions without granting a hearing and the significant likelihood that hearings would not even be requested for many of the substances suggest that the burden on the agency would be modest. Although the FDA contends that, under respondents' interpretation, it might also be required to issue tolerances for substances which occur in foods in such negligible amounts that they cannot be detected or have not yet been discovered, this contention is based on speculation and ignores a number of judicial precedents which suggest that section 406 may not apply to such substances.

The FDA accurately points out that it would have less flexibility in regulating contaminants through tolerances since, once a tolerance is issued, food producers may sell food with contaminants below the tolerance level without fear of prosecution. However, this scheme, which essentially amounts to giving food producers a license to sell foods with a certain amount of contaminants, is the same scheme that Congress chose for similar substances which are sanctioned by the FDA for use in foods. It is also unlikely that the FDA would ever need to act on an emergency basis to lower a tolerance for an added unavoidable contaminant, since such substances have been identified in the environment for a long time. If there were ever such an emergency, the agency has the ability to revoke a tolerance on an expedited basis.

In any event, the FDA totally ignores the benefits of using section 406 to regulate substances such as aflatoxins. Under its current practice, each time the FDA brings a case based on a violation of an action level, it must prove as a fact that food contaminated with aflatoxins "may be injurious to health." On the other hand, if there were a tolerance for aflatoxins, the only issue in an enforcement proceeding would be whether the level of the contaminant exceeds the tolerance. Moreover, by permitting public participation, the agency would make more informed decisions regarding the regulation of substances which are poisonous or deleterious when added to foods. The important point, however, is that, regardless of the merits of either method, Congress explicitly chose to require the FDA to use tolerances issued under sections 406 and 701(e).

Finally, the Pesticide Amendments of 1954 demonstrate that the FDA should be required to convince Congress of the merits of its position if it desires to change section 406 from "shall" to "may." The FDA successfully made such a case in 1954 with regard to pesticides, and as a result Congress exempted pesticides from section 406 by creating a new, more expeditious procedure for regulating them. The fact that the FDA believed it needed a congressional amendment to section 406 in order to use different procedures to set the allowable levels for pesticides highlights the error of its argument that the procedural requirements in section 406 and 701(e) are merely permissive. Moreover, the fact that Congress left section 406 in place for all other contaminants further demonstrates that Congress intended the FDA to provide an opportunity for public participation under section 701(e) before it establishes the permissible levels of aflatoxins and other unavoidable contaminants.

ARGUMENT

SECTION 406 OF THE FDC ACT REQUIRES THE FDA TO ALLOW PUBLIC PARTICIPATION PRIOR TO AUTHORIZING UNAVOIDABLE CONTAMINANTS THAT ARE ADDED TO FOODS.

A. The Language and Structure of the FDC Act Require the FDA to Comply With Formal Rulemaking Procedures Before Approving Added, Unavoidable Contaminants in Foods.

Section 406 of the FDC Act states that:

> [any] poisonous or deleterious substance added to any food *except where such substance* is required in the production thereof or *cannot be avoided by good manufacturing prac-*

tice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [the adulteration provision].

21 U.S.C. § 346 (emphasis supplied). The parties agree that aflatoxins in corn are an added substance which is poisonous or deleterious within the meaning of the Act and that the Act prohibits the sale of corn containing aflatoxins unless the substance falls within one of the exceptions contained in section 406. One exception applies to substances which "cannot be avoided by good manufacturing practice," and the parties also agree that aflatoxins are such a substance. J.A. 148, 150.

If Congress had stopped at the portion of the statute quoted above, then section 406 would not apply to aflatoxins or to other unavoidable substances. In that event, aflatoxins would be regulated only by section 402(a)(1), which deems any food to be "adulterated" if it contains an added substance which "may render it injurious to health." 21 U.S.C. § 342(a)(1). Since there is no known safe level of aflatoxins, the FDA would have a very strong argument that the shipment of food with any detectible level of the substance violates section 402(a)(1) and hence section 301(a). However, given its other responsibilities, the FDA, in the exercise of its discretion, might not proceed when a violation was technical but trivial. *Heckler v. Chaney, supra.*

Relying on section 402(a)(1) alone to set the adulteration standard for foods with unavoidable contaminants would create two problems. First, food processors would be continually at jeopardy since they would have no guarantee as to how the agency intended to exercise its discretion. Second, the FDA would be limited to bringing individual enforcement actions and in each case would have to carry the burden of proving that the level of the contaminant in the food at issue "may render it injurious to health." This approach would require the FDA to use considerable resources and would also create a risk of inconsistent results, which is inherent whenever issues of fact must be established *de novo.* For this reason, at hearings on the original version of the FDC Act, Walter Campbell, Chief of the FDA,

testified that the case-by-case method was inadequate for the regulation of added, unavoidable contaminants. *Foods, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce,* 73d Cong., 2d Sess. 19-21 (1933) (hereinafter *"1933 S. 1944 Hearings"*). The Agency therefore requested that Congress give it the authority to issue tolerances which would have the force of law, which Congress did in sections 402(a)(2)(A) and 406. Section 402(a)(2)(A) states that a food is "adulterated" if "it bears or contains any added poisonous or added deleterious substance. . .which is unsafe within the meaning of section 406." Section 406 in turn provides that if an added "poisonous or deleterious substance" is "required or cannot be. . . avoided,"

> the Secretary *shall* promulgate regulations limiting the quantity therein or thereon *to such extent as he finds necessary for the protection of public health.*

21 U.S.C. § 346 (emphasis supplied).

A tolerance promulgated under section 406 is binding on both food producers and the FDA. Thus, if a food contains a poisonous or deleterious substance in an amount exceeding the tolerance, section 406 declares that it "shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a)." In that event, the FDA need not present evidence on safety in court, but it need only show that the amount of the substance found in foods exceeds the tolerance level set under section 406.

On the other hand, the statutory scheme protects food producers if the level of the added substance is below the tolerance. Thus, since section 406 deems added, unavoidable contaminants "unsafe" only if a tolerance is exceeded, section 402(a)(2)(A) does not apply if the level of the contaminant is below the tolerance level. Likewise, section 406 explicitly states that while a tolerance is in effect, a "food shall not. . . be adulterated within the meaning of clause (1) of section 402(a)," which provides that foods are adulterated if they contain a substance which "may render it injurious to health." Thus, sec-

tion 406 both conserves FDA resources by eliminating the need to litigate in each case whether a substance may be injurious to health, and it protects a food producer from an adulteration charge under either section 402(a)(1) or 402(a)(2)(A), so long as its products comply with the tolerance level.

Relying on the words "shall promulgate regulations," the court of appeals held that section 406 requires the FDA to issue regulations when it decides to approve the sale of foods containing a substance such as aflatoxins. Pet. App. 6a. This interpretation follows directly from the plain meaning of section 406. According to *Webster's Ninth New Collegiate Dictionary* 1081 (1985), the word "shall" is "used in laws. . . to express what is mandatory." An example provided by *Webster's* is "it shall be unlawful to carry firearms." *Id.* Just as one would have to ignore the plain meaning of that legal command to read "may" for "shall," the FDA's argument that the FDC Act only "authorizes," rather than compels, it to promulgate regulations contradicts the plain meaning of section 406. Indeed, perhaps for this reason, the FDA conceded in its petition to this Court that the interpretation of section 406 adopted by the court of appeals is "entirely rational and plausible." Pet. 8.

The principal argument which the FDA advanced below was that the second italicized portion of section 406—"to such extent as he finds necessary for the protection of public health"—modifies the word "shall," and therefore that section 406 merely gives the Secretary the discretion to issue tolerances, rather than compelling him to do so. The flaw in this argument is that it has no support in the language of the statute or in the structure of section 406. As the court of appeals explained, it is "clear from the structure of the sentence at issue here that the phrase relied upon by the Secretary simply does not modify the pivotal word 'shall.'" Pet. App. 7a. If Congress had intended the qualifying language to modify "shall," it would have placed the qualification adjacent to that word. However, Congress placed that phrase where it did because it intended "the qualifying phrase [to serve] an entirely different office; it explains the standard that the Secretary is to employ in setting the tolerance." *Id.*;

see United States v. General Foods Corp., 446 F. Supp. 740, 745 (N.D.N.Y.), *aff'd*, 591 F.2d 1332 (2d Cir. 1978)("Congress has apparently *mandated* that the F.D.A. establish tolerances for poisonous or deleterious substances which are required or unavoidable in the production of food")(emphasis supplied).

Other provisions in the Federal Food, Drug, and Cosmetic Act, which Congress enacted in 1938, also demonstrate that Congress intended the word "shall" to have its customary meaning. Section 406(b) directed that "the Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food. . . ," and section 604 contained an identical provision for cosmetics. FDC Act §§ 406(b), 604, *repealed by* Color Additive Amendments of 1960, 21 U.S.C. § 376. Similarly, in section 501(b) Congress directed that, if the Secretary concludes that tests to measure the purity of a particular drug are not in an official compendium or if those tests are inadequate, "the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium," and if that body fails to prescribe tests within a reasonable time, "the Secretary shall promulgate regulations" prescribing the appropriate tests. Again Congress used the word "shall" to direct the Secretary to undertake certain acts, including the promulgation of regulations through formal rulemaking (*see* section 701(e)), but under the FDA's construction of the statute it could choose never to follow these statutory commands.

Section 401 is illuminating both because it also uses the word "shall" and because, in contrast to section 406, Congress softened its command by giving the Secretary a limited amount of discretion. Thus, section 401 declares that "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations. . . establishing for any food a reasonable definition and standard of identity. . . ." As this Court held in *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 228 (1942), "[t]he statute *requires* the Administrator to adopt standards of identity which in his judgment 'will' promote honesty

and fair dealing in the interest of consumers" (emphasis supplied). Thus, "[a]cting within his statutory authority he is *required* to establish standards which will guard against the probable future effects of present trends." *Id.* (emphasis supplied). Just as section 401 requires the FDA to adopt regulations establishing standards of identity, which under section 701(e) must also be issued through formal rulemaking, section 406 requires the FDA to promulgate regulations setting tolerances for unavoidable contaminants.

Section 401 also undercuts the FDA's argument that the words "necessary for protection of the public health" in section 406 modify the word "shall." As we have previously pointed out, if Congress had intended to give the FDA discretion to issue tolerances, it would have placed the description of that discretion adjacent to the word "shall." This is precisely the approach it took in section 401, when it began that provision with the qualification "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers," which further demonstrates that the standard to be applied in section 406 was not intended to modify the word "shall."

In this Court, the FDA raises two new arguments to support its contention that the structure of the FDC Act supports its interpretation of section 406. Because these contentions were not presented to the panel below, they were not discussed by the court of appeals. The first new argument is that if, as respondents contend, the FDA must issue regulations for all unavoidable poisonous and deleterious substances, then the portion of section 402(a)(1) applicable to added contaminants would be superfluous. Br. 23-25. Relying on the canon of construction that no provision in a statute should be interpreted as being superfluous, the agency contends that section 406 should be interpreted as simply granting it the authority to issue tolerances, rather than directing it to do so.

However, this argument is without merit since, even if section 406 is interpreted as being mandatory, section 402(a)(1) still applies to poisonous and deleterious additives for which the

FDA has not yet issued a tolerance. For example, on the day that the 1938 statute went into effect, the FDA did not have any tolerances in place. Moreover, in subsequent years, more poisonous and deleterious added substances have been identified. But even under respondents' construction of the statute, these substances cannot be regulated under section 406 until the agency has complied with section 701(e). Indeed, this was precisely the status of aflatoxins when their carcinogenicity was discovered in the 1960's, yet the FDA could properly have proceeded against them under section 402(a)(1), pending the promulgation of a tolerance under sections 406 and 701(e). Therefore, since section 402(a)(1) may be used to regulate added contaminants during the interim before a tolerance can be established, it is not superfluous, and thus respondents' construction of the statute would not "jettison" the "case-by-case method of proving adulteration under *Lexington Mill*" (*see* Pet. Br. 30-31). *See United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).[4]

The FDA resists respondents' argument that one of the uses of section 402(a)(1) is to act as a transitional provision before a tolerance is promulgated, by pointing out that the Color Ad-

[4] Even under the FDA's argument, the case-by-case method of proving adulteration under *Lexington Mill* would survive for inherent contaminants covered by section 402(a)(1). This is because section 402(a)(1) applies to both added and inherent contaminants, whereas section 406 applies only to added substances.

For similar reasons, the lower court decisions cited on page 19 of the FDA's brief have no bearing on the issues raised here. Thus, for example, in *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), the court held that the FDA may use its authority under section 402(a)(1) to initiate enforcement proceedings to enjoin the shipment of corn containing aflatoxins in excess of the 20 ppb action level. In the course of its opinion, the Fifth Circuit stated that "the FDA either may adopt formal regulations [under section 406 of the FDC Act], or may litigate the alleged violations on a case-by-case basis." *Id.* at 151. However, that court was not presented with the question of whether section 406 requires the FDA to use formal rulemaking, as opposed to action levels, in establishing permissible levels of unavoidable contaminants such as aflatoxins. Similarly, as the court of appeals indicated (Pet. App. 15a), the same point distinguishes *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958), which was an enforcement action brought for violation of the adulteration provision that prohibited the sale of coal-tar dyes which had not been certified by the FDA.

ditive Amendments, which Congress enacted more than 20 years after it enacted section 406, contain specific transitional provisions. Br. 25; Pub. L. No. 86-618, § 203, 74 Stat. 404-07 (1960). However, in the 1938 Act, Congress did not include transitional provisions similar to those in the Color Additive Amendments. Instead, it used the standards in the 1906 Act to accomplish the transition by incorporating the 1906 standard into the statute (as in the case of section 402(a)(1)), by explicitly exempting products which were subject to the 1906 Food and Drugs Act (as in the case of drugs, 21 U.S.C. § 321(p)(1)), and by delaying the effective date of the 1938 Act (FDC Act § 902(a)). Therefore, the absence of specific transitional provisions in the 1938 Act has no bearing on the question of statutory interpretation presented in this case.

The FDA's second new argument is that, under the decision below, since FDA has not issued any tolerances under section 406, all foods containing unavoidable contaminants (which the FDA argues is virtually the entire food supply) are *per se* adulterated under sections 402(a)(2)(A) and 406. Br. 14, 22-23, 25, 34, 49. To support this argument, the FDA asserts that "under the court of appeals' interpretation, if a tolerance is *not* in effect, a food is 'unsafe' under section 406 and thus adulterated under Section 402(a)(2)(A)." Br. 25 (emphasis in original). The FDC Act does not require this result, nor did the opinion below.

Under section 402(a)(2)(A), a food is adulterated if it contains a "poisonous or deleterious substance" which is "unsafe within the meaning of section 406." Under section 406, such a substance is "unsafe" when it is "added to any food" unless the substance falls into the exception for substances which are "required" or "cannot be avoided." As to unavoidable additives, section 406 directs the FDA to issue formal tolerances, and it declares that "any quantity exceeding the limits *so fixed* shall also be deemed to be unsafe for purposes of [section 402(a)(2)(A)]" (emphasis supplied). Therefore, under the statute, a food is "unsafe" within section 402(a)(2)(A) *only* if it contains an avoidable, added contaminant, or if it contains an unavoidable contaminant at levels in excess of a tolerance that

has been "fixed" by the FDA. While the plain language of section 406 requires the FDA to issue tolerances for substances such as aflatoxins, neither section 406 nor section 402(a)(2)(A) renders unavoidable added contaminants "unsafe" if there is no tolerance in effect. As explained above, pages 20-22, *supra*, those substances may still be regulated by section 402(a)(1), but foods containing them are prohibited only if the FDA can demonstrate that they contain contaminants at levels which "may be injurious to health."[5]

Nor is the FDA correct in the assertion, made throughout its brief, that the court of appeals reached a contrary construction of the statute. The only citation which the FDA gives for its interpretation of the lower court's opinion is the portion of the opinion which appears at Pet. App. 15a (Br. 49). There the court restated its conclusion that:

> the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of [section 402(a)(1)] or unsafe for purposes of [section 402(a)(2)(A)].

Fairly read, in the context of respondents' claim that the FDA may not use action levels to *approve* unavoidable added contaminants, the court stated only that the agency must use section 406 when it decides to grant an exemption from the adulteration provisions in section 402(a)(1). It further held that section 402(a)(2)(A) does not apply unless the FDA has promulgated a tolerance. Thus, neither the overall statutory scheme, nor the lower court's opinion, supports the FDA's argument that interpreting section 406 to require the agency to issue tolerances

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[5] Although the court of appeals did not reach this issue, respondents have at times suggested a broader construction of section 406, under which foods would be *per se* "unsafe" if the FDA had not issued a tolerance under section 406. However, respondents do not advocate such a construction here since, under the plain meaning of the statute, section 406 does not cause substances to be "unsafe" simply because no tolerance has been issued.

leads to the conclusion that in the interim all foods that contain substances covered by section 406 are adulterated.[6]

In addition to these new arguments, the FDA adheres to its position that its construction is entitled to substantial deference because it is the expert agency charged with enforcing the FDC Act. However, until relatively recently, the agency never offered an opinion on whether it is required to promulgate tolerances under section 406. The early interpretations quoted in the agency's brief (Br. 17-18 & n.14), its quotations from *Flemming v. Florida Citrus Exchange, supra* (Br. 18), and the quotations from the legislative history (*see* pp. 29-30, *infra*) only acknowledge that the FDA has the authority to issue tolerances under section 406, without resolving the issue of whether it is required to do so.

Even if the FDA had consistently construed section 406 as it does in this action, no deference should be given to the agency's interpretation because the "intent of Congress is clear [and] the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron v. Natural Resources Defense Council*, 104 S. Ct. 2778, 2781-82 (1984); *see also Chemical Manufacturers Association v. Natural Resources Defense Council*, 105 S. Ct. 1102 (1985). Here, by "employing the traditional rules of statutory construction," the Court can ascertain "that Congress had an intention on the precise question at issue," and therefore "that intention is the law and must be given effect." *Chevron v. Natural Resources Defense Council, supra*, 104 S. Ct. at 2782 n.9. Thus, the agency's interpretation of section 406 cannot be upheld because it undercuts the plain meaning of the statute.

There are several other factors which suggest that the FDA's construction here should be accorded less deference than is often the case. First, the FDA's construction eases the regulation of harmful substances in foods. As this Court held in *United States*

[6] There is no inconsistency between respondents' construction of the statute and this Court's decision in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958). *See* Pet. Br. 22. As petitioner points out, this Court stated in *Flemming* that "[t]he existence of a tolerance is specifically stated in § 406(a) [currently § 406] only to give sanction to what would otherwise amount to adulteration within the terms of § 402(a)(1)." 358 U.S. at 166. Respondents agree.

v. An Article of Drug, 394 U.S. 784, 798 (1969), "we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." Thus, consistent with this purpose, the Court should construe section 406 to require the FDA to use formal rulemaking, rather than action levels, to authorize added poisonous and deleterious substances in foods.

Second, the deference given to administrative agencies is based, at least in part, on the expertise which those agencies bring to questions of administrative law. However, where the question of statutory interpretation does not depend on a complex, scientific question, the justification for deference is diminished, and accordingly the Court should be less willing to defer to the agency. *See, e.g., Barlow v. Collins*, 397 U.S. 159, 166 (1970). Third, the deference accorded an agency should be tempered where the agency's construction would lessen the burdens which a statute would otherwise place upon it. Here the FDA advocates a construction of the Act which would relieve it of any obligation to engage in public proceedings regarding substances covered by section 406. Since it is in the FDA's self-interest to advocate this construction, the Court should accord it less deference than it would in the ordinary case.

* * *

The irony of the FDA's position on statutory construction is that the principal rationale that it offers for its interpretation of the FDC Act is that the statute must be construed to avoid making section 402(a)(1) superfluous for added contaminants, and yet the result it champions would enable the agency to continue to avoid using section 406 altogether. The irony of this position is further underscored by the agency's reference to the 1933 testimony of FDA Chief Walter Campbell that the tolerance provision in section 406 was "one of the more important provisions of [the] bill" (Br. 28), and yet the FDA has used that provision only twice in 48 years. 9 Fed. Reg. 11836 (1944)(the pesticide flourine spray residues); 21 C.F.R. §§ 109.30, 509.30

(1985)(polychlorinated biphenyls ("PCBs")). At bottom, what the agency's arguments ignore is that Congress provided a very specific method for approving levels of added, unavoidable contaminants: tolerances promulgated under section 701(e). Therefore, by stating that the FDA "shall promulgate regulations" setting limits for these substances, Congress could not have been clearer in its intention that the FDA use only the procedures in sections 406 and 701(e) to approve substances such as aflatoxins.

B. The Legislative History of the 1938 FDC Act Is Consistent With the Plain Meaning of Section 406.

Since the plain language of sections 406 and 701(e) requires the FDA to establish permissible levels of poisonous and deleterious substances that are added to foods only through the issuance of tolerances, this Court need not go beyond the words of the statute to determine that the court of appeals was correct. *Caminetti v. United States*, 242 U.S. 470, 485 (1917)("Where the language is plain and admits of no more than one meaning, the duty of interpretation does not arise, and the rules which are to aid doubtful meanings need no discussion.")

In any event, the legislative history confirms that Congress intended to direct the agency to establish tolerances for unavoidable contaminants only through the formal rulemaking process. Indeed, the legislative history shows that Congress chose language requiring the FDA to set section 406 tolerances for unavoidable, added contaminants after specifically rejecting statutory language which would have merely authorized it to do so. In order to understand precisely how Congress changed the federal laws applicable to adulterated foods in 1938, it is necessary to review briefly the 1906 Act and how the FDA regulated poisonous substances prior to 1938.

Under the 1906 Federal Food and Drugs Act, the FDA's approach to regulating adulterated foods was strikingly similar to the approach that it uses today. Thus, the statute declared a food to be adulterated "[i]f it contain[ed] any added poisonous or other added deleterious ingredient which may render such article injurious to health." 1906 Federal Food and Drugs Act § 7 34 Stat. 770, *repealed by* FDC Act § 902(a). This standard was later incorporated into section 402(a)(1) of the 1938 FDC Act.

Prior to 1938, the FDA had adopted "administrative tolerances" for poisonous and deleterious substances. *1933 S. 1944 Hearings* 22. Those tolerances, like the FDA's current action levels, were issued without notice to the public or an opportunity to comment. While there is no conclusive evidence on this point, the term suggests that, like action levels, administrative tolerances also amounted to a license to market foods as long as the contaminants were below the tolerance level.

Congress adopted the 1938 FDC Act after five years of hearings and debates. As the FDA indicates (Br. 29), the original version of the Act used the word "shall" to describe the agency's obligation to promulgate regulations. S. 1944, 73d Cong., 1st Sess. § 11(a) (1933). Thus, as FDA Chief Campbell testified, under the tolerance provision, "tolerances must be established for fruits and vegetables." *1933 S. 1944 Hearings* 118. The most important aspect of this provision was that for the first time it "authorized" the FDA to issue binding regulations, and perhaps it was for this reason that agency officials used the word "authority" to describe the new power which section 406 would confer upon the agency. *See* Pet. Br. 28. In addition, most of the bills introduced between 1933 and 1937 used the words "is authorized to" in describing the FDA's obligation to issue tolerances for added contaminants. *See* Pet. Br. 30 nn.29, 30. Thus, many of the witnesses who testified at hearings held between 1933 and 1937, and who stated that the bills "authorized" the FDA to adopt tolerances, were accurately describing bills under consideration at the time of their testimony. Pet. Br. 29-31 & nn.24, 28.

The bill which Congress enacted as the FDC Act of 1938 was introduced in the Senate in January 1937. S. 5, 75th Cong., 1st Sess., 81 Cong. Rec. 65 (1937). Section 15(a) was similar to section 406 as enacted in that it declared added, poisonous substances to be "unsafe" unless the substance is required or cannot be avoided. For substances falling within the exception,

however, section 15(a) provided that "the Secretary *is authorized to promulgate* regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health" (emphasis supplied). Section 24(e) of the bill would have afforded the public substantially the same notice and hearing rights as provided by section 701(e) of the FDC Act. With minor changes not relevant here, the "is authorized to" language was approved by the Senate. 81 Cong. Rec. 2019 (1937).

If Congress had adopted the Senate bill, respondents would have no claim under section 406. However, the House Committee on Interstate and Foreign Commerce made a number of changes before the measure was adopted by the House. One of those changes substituted the word "shall" for the words "is authorized to" in section 406(a). House Committee on Interstate and Foreign Commerce, 75th Cong., 1st Sess., S. 5 § 406(a) (Confidential Comm. Print No. 2, 1937), *reprinted in A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments*, Vol. V at 767, 792 (U.S. Dep't of Health, Education, and Welfare) (hereinafter "*FDC Act Legislative History*"). In addition, the House Committee changed the words "is authorized to" to "shall" in four other places in that Committee Print. *Id.* §§ 401, 406(b), 501(b) & 604. *See also* discussion at pp. 19-20, *supra.*

Neither the House Report, nor the Conference Report, nor any of the statements subsequently made in the Congressional Record directly discusses the reasons for these changes. All that is known is that, in each case, where the Senate bill had used the words "is authorized to," the change to "shall" adopted by the House became law. FDC Act §§ 401, 406(b), 501(b) & 604; *see* 21 U.S.C. §§ 341, 351 (Sections 406(b) and 604 were repealed by the Color Additives Amendments of 1960, 21 U.S.C. § 376.). The fact that the House made these changes in the legislation should be given considerable weight in identifying Congress's intent, since it shows a conscious decision by Congress to use the mandatory word "shall." *See, e.g., Gulf Oil Corp. v. Copp*

Paving Co., 419 U.S. 186, 200 (1974) (change made by Conference Committee "strongly militates against a judgment that Congress intended a result that it expressly declined to enact"); *Pan American World Airways, Inc. v. CAB*, 380 F.2d 770, 781 (2d Cir. 1967) ("[t]hat Congress adopted the House version of the bill, specifically rejecting the Senate's conflicting version, is of course an extremely significant factor in determining what was Congress' intention").

Despite this legislative history, the FDA relies on the following general language from the House Report to support its argument that the House Committee's change from "is authorized to" to "shall" was not intended to require the FDA to issue tolerances under section 406:

> This subsection first prohibits the unnecessary addition of poisons. Where such additions are necessary, the establishment of tolerances is authorized, based upon the practical necessities for the use of poisonous substances.

H.R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (1938). The FDA also relies on similar statements made during the floor debates on the House bill. Br. 33 & n.35. There are several reasons, however, why those general statements are of no help to the FDA on the issue before this Court.

First, the statements are consistent with respondents' interpretation and the literal language of the statute. Thus, the significant aspect of the tolerance-setting provision was that Congress for the first time conferred authority on the FDA to issue regulations which would establish the permissible limits for unavoidable contaminants. Therefore, the principal focus of attention by everyone, including the FDA, was in creating this new authority, not in the procedures that would be utilized in carrying it out. In any event, the fact that the House Committee Report only described the new statute as "authority" given to the agency is consistent with this legislative history and does not undercut the plain language of the statute, which directs the

FDA to use that authority when granting permission to sell foods with unavoidable contaminants in them.[7]

The FDA's argument is further undercut by the four other provisions where the House Committee changed the words "is authorized to" to "shall." *See* pp. 19-20, *supra*. In each case Congress enacted that change into law, but in each case the House Committee Report described the provision as "authorizing" the agency to exercise some new authority. Undoubtedly, for each of these provisions, one could conduct an exercise similar to the one conducted by the agency here and find numerous instances in the legislative history, as well as statements by commentators on the statute, where the statutory provision was described in terms of the "authority" it conferred on the agency. However, the fact that section 406 and these other four provisions in the FDC Act were less than fully described by those seeking to give them a shorthand characterization in the House Committee Report cannot be a sufficient justification for changing the word "shall" into the permissive language that the FDA advocates. Yet this is precisely the argument which the FDA advances in urging the Court to interpret section 406 as though it were never amended by the House to direct the agency to issue regulations for unavoidable contaminants that are added to foods.

In summary, the FDA's interpretation of the legislative history here amounts to a contention that this Court should ignore the word "shall" in section 406 because there is no discussion in the hearings or committee reports which specifically confirms the clear mandatory language in the Act. However, the fact that Congress considered two versions of section 406, and ultimately amended that section to make it mandatory, is far more significant than the absence of a discussion of this aspect of section 406 in the legislative history. Thus,

[7] It is also relevant that the phrase "to such extent as he finds necessary for the protection of public health" was included in the version of S. 5 adopted by the Senate. S. 5, 75th Cong., 1st Sess. § 15(a) (March 10, 1937), *reprinted in FDC Act Legislative History*, Vol. V at 633, 655. The fact that S. 5 used the word "authorized" to describe the authority conferred on the Secretary demonstrates that the phrase was included to describe the standard for setting tolerances, rather than to qualify the word "shall," as the FDA argues. Br. 17.

because the FDA's interpretation of section 406 amounts to a rewriting of the statute and is contrary to the clear, overall Congressional intent, it should be rejected.

C. The FDA's Policy Arguments Are Not A Basis for Overriding the Plain Meaning of Section 406.

In an effort to convince this Court to disregard the language of the statute, the FDA relies on a number of policy considerations. First, the FDA contends that section 406 could also apply to a "whole universe" of substances which occur in only "negligible amounts," many of which are "undetectable using currently-available analytical methods" and others which "may yet be undiscovered." Br. 47 n.49. Not only has the FDA neglected to identify any such substance, but even assuming there were such substances, they would not necessarily be covered by section 406. Thus, if such a substance appeared in minuscule amounts, which could not have been detected in 1938, it arguably may not be "poisonous or deleterious" within the meaning of section 406. Other courts have reached similar conclusions in analogous cases under the FDC Act where new detection methods could literally prohibit foods containing negligible amounts of contaminants that pose no threat to the public health.

For example, in interpreting section 402(a)(3), 21 U.S.C. § 342(a)(3), which prohibits "filthy, putrid, or decomposed substance[s]" in food, the Fifth Circuit has recognized that that section "sets a standard that if strictly enforced, would ban all processed food from interstate commerce" because a "scientist with a microscope" could find such a substance "in almost any canned food we eat." *United States v. 484 Bags, More or Less*, 423 F.2d 839, 841 (5th Cir. 1970), *quoting United States v. 1500 Cases, Etc.*, 236 F.2d 208, 210-11 (7th Cir. 1956). Nevertheless, "the majority, in fact almost unanimous, rule is that the Act confers the power to exclude from commerce all food products which contain in any degree filthy, putrid or decomposed substances," although such "harsh consequences...are tempered by discretion given the Secretary." 423 F.2d at 839 (citations omitted).

Any "harsh consequences" of the court of appeals' decision in this case could also be tempered in the same manner. *See also Developments in the Law—The Federal Food, Drug, and Cosmetic Act,* 67 Harv. L. Rev. 632, 644-45 (1954) (If section 402(a)(3) "were interpreted literally, almost every food manufacturer in the country could be prosecuted," and therefore, "recognizing that some contamination may be inevitable and *de minimis,*" courts have held that section 402(a)(3) does not apply to "a negligible amount of filth or decomposition unavoidable even with the highest care."); *Monsanto v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979) (negligible amount of substance may be *de minimis* and not a food additive subject to FDC Act §§ 201(s), 409, 21 U.S.C. §§ 321(s), 348); *Scott v. FDA*, 728 F.2d 322, 325 (6th Cir. 1984)(negligible amount of a contaminant in a color additive not subject to anti-cancer clause, FDC Act § 706(b)(5)(B), 21 U.S.C. § 376(b)(5)(B)). Thus, if faced with a similar issue in the context of section 406, a court might reach an analogous result.

In any event, the Court need not rule on the status of these unidentified substances. Instead, this case presents the question of whether the FDA may use action levels to grant what amounts to a license to market foods containing added substances that are known carcinogens, without any public participation, in the face of the plain language of section 406 and the formal rulemaking requirements in section 701(e). Thus, if there are certain unavoidable, added contaminants for which the agency does not even have action levels, the legality of the agency's method of regulating them is simply not at issue here.

Second, the FDA argues that its approach is preferable because formal tolerances might impair its ability to react in the event of an emergency. Br. 44-45. However, the agency has not pointed to a single example of when it has lowered an action level because an emergency has arisen, and respondents are aware of none. Thus, the most likely reason that Congress did not include an emergency provision in section 406, similar to the "imminent hazard" provision applicable to drugs (21 U.S.C. § 355(e)), is that it was not concerned about an emergency arising with respect to known contaminants, which have been in the

environment for a long period of time, and which typically occur in small quantities. In fact, other than the provision applicable to new drugs, Congress did not include emergency authority in any other portion of the 1938 FDC Act. Even subsequent amendments establishing licensing schemes for food and color additives do not give the FDA the authority to act quickly to remove those substances from the market after they have been approved. 21 U.S.C. §§ 348, 376. In any event, if there were truly an emergency, the FDA could act on an expedited basis to modify its tolerance under section 701(e). *See Pennsylvania Gas & Water Co. v. FPC*, 427 F.2d 568, 576 (D.C. Cir. 1970)(agencies have latitude to expedite hearings in the public interest). Therefore, the theoretical argument that the FDA might sometime in the future wish to use emergency authority provides no support for the agency's rewriting of section 406.[8]

Third, the FDA argues that the court of appeals construction places an undue administrative burden on it. Br. 45-48. However, the FDA takes the position that it has issued action levels under section 406 for only eight contaminants, which in turn are present in 21 foods.[9] More importantly, in many respects, the procedures required by sections 406 and 701(e) are

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[8] The FDA's current regulations provide that it will use action levels only in "dynamic circumstances," *i.e.*, when it is impracticable to set tolerances (Br. 7). Even this use of action levels is limited to situations where "technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance." 21 C.F.R. §§ 109.6(c), 509.6(c)(1985). *See also* 42 Fed. Reg. 53814, 53817 (1977)(J.A. 68) ("[A]n action level is appropriate if industrial practices are improving so quickly that the extent to which a substance is avoidable changes significantly from year to year, or if toxicological data are scanty or conflicting but additional data are being developed.") However, aflatoxins plainly do not meet these criteria. More than 10 years ago when it proposed to issue a tolerance for aflatoxins in peanuts, the FDA explained that action levels are "appropriate when changes are foreseeable in the near future that might affect the appropriateness of the limitation established," but that this "is not the case with aflatoxin." J.A. 47. The fact that the agency has not changed the action level for aflatoxins since 1969, and the fact that, with the single exception of PCBs in packaging materials, the FDA regulates all unavoidable contaminants with action levels, also demonstrate that the FDA has not even followed its own regulations concerning the use of tolerances and action levels.

[9] In addition, there are 15 substances for which the FDA has set action levels (J.A. 148), but which the agency apparently contends are subject to section 408 of the FDC Act, 21 U.S.C. § 346a. *Compare* Pet. Br. 47 n.48 *with* 21 U.S.C. § 346a.

not very different from the notice and comment procedures required by the informal rulemaking requirements of the APA. The only significant difference is that section 701(e) requires the agency to hold a hearing before an administrative law judge where there are disputed issues of material fact.

However, it is far from certain that anyone will even request a hearing on any of these substances, or that the FDA would be obliged to hold one. For example, other provisions of the FDC Act require a hearing on decisions pertaining to prescription drugs, food additives, and a variety of other products regulated by the agency. 21 U.S.C. §§ 348(f), 355(e), 376(d). *See* Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 Mich. L. Rev. 171, 208 (1978) ("[t]he statutorily prescribed process for approving or withdrawing approval of a food additive is as complex as that required for the establishment of tolerances under section 406"). Even though thousands of products fall within these provisions, the hearing requirement has not paralyzed the FDA because, in most cases, the agency denies the application for a hearing and issues a summary decision, a procedure which this Court upheld in *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620-22 (1973). For example, although the agency has withdrawn 1,116 new drug applications since 1962, it has held only 13 evidentiary hearings concerning such decisions.[10] Therefore, there simply is no basis for assuming that if the FDA were to follow the plain language of section 406, it would be required to hold hearings for even the eight added substances for which it currently has action levels.[11]

[10] These figures were supplied to respondents by counsel for the Food and Drug Administration.

[11] The agency also argues that the burden of issuing formal regulations is demonstrated by the fact that it took the FDA seven years to issue the tolerance for PCBs. However, the FDA has been repeatedly criticized by the courts for its delays in reaching decisions. *See, e.g., Contact Lens Manufacturers Association v. FDA*, 766 F.2d 592, 603 (D.C. Cir. 1985); *General Medical Co. v. FDA*, 770 F.2d 214, 216 (D.C. Cir. 1985); *American Public Health Association v. Veneman*, 349 F. Supp. 1311, 1317 (D.D.C. 1972). Therefore, the amount of time taken to issue a single tolerance is not indicative of how long the agency should reasonably require to comply with sections 406 and 701(e).

In any event, in making this policy argument, the FDA totally ignores the benefits of issuing regulations. Under its current practice, the FDA must prove that corn contaminated with aflatoxins above 20 ppb is adulterated, each time that it brings an action for violation of the action level. *See, e.g., United States v. Boston Farm Center, Inc., supra*. On the other hand, if there were a formal tolerance in effect, the FDA would only have to show that the level of aflatoxins exceeded the tolerance, and any challenge to the tolerance would have to be made directly rather than as a defense to a court action. Thus, while the agency obviously uses resources to set the tolerance, it would save resources in the long run when prosecuting companies for violating the regulation. Also, by permitting public participation, the agency could make more informed decisions regarding the regulation of known carcinogens like aflatoxins.

The Court need not, and should not, resolve the debate between the parties about which public policies are most important. Instead, it is sufficient that Congress could rationally have chosen to require the FDA to issue tolerances for contaminants, and therefore the agency's policy arguments should not be relied upon to avoid the plain meaning of the statute.

D. The Legislative History of the 1954 Pesticide Amendments Supports the Plain Meaning of Section 406.

Unable to sustain its position on the basis of the language of section 406, the FDA has resorted to the argument that, through subsequent action, Congress has sanctioned FDA's use of action levels in regulating added contaminants. On this basis, the FDA argues that its construction of the statute is entitled to "enhanced deference." Br. 39. For this proposition, it relies principally on the legislative history of the 1954 Pesticide Amendments to the FDC Act. FDC Act § 408, 21 U.S.C. § 346a. However, rather than support the FDA's position, the legislative history of these Amendments supports respondents' position. That history demonstrates that the FDA concluded that a statutory amendment was required to permit the agency to deviate from the rulemaking requirements specified in section 406. Moreover,

the history of the 1954 Pesticides Amendment further demonstrates that if there were strong policy reasons for not abiding by a statutorily prescribed regulatory scheme, the appropriate forum for addressing those concerns would be Congress, not the courts.

Prior to the 1954 Pesticide Amendments, pesticides were subject to section 406 of the 1938 Act. Thus, pesticides were poisonous or deleterious substances that were added to foods, but which were "required" within the meaning of that section, since pesticides are needed so that agricultural products can survive the ravage of insects. *See, e.g.*, H.R. Rep. No. 1385, 83d Cong., 2d Sess. 2-3 (1954). Although the FDA had in 1944 issued one formal tolerance for a pesticide under section 406 (Pet. Br. 46 n.46), its resources had been diverted to World War II in the mid-1940's. For that and other reasons, the FDA did not begin to set formal tolerances for pesticides on a wholesale basis until the mid-1950's. *See* Testimony of Charles W. Crawford, FDA Commissioner, *Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 4277 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. 121 (1953)(hereinafter "*1953 Pesticide Hearing*"). However, by that time, largely due to advances made in the chemical industry as a result of the war, there were hundreds of new pesticides that agricultural producers wanted to use on their products, but for which there were no FDA-sanctioned tolerances. *Id.*

In 1950, the FDA began a rulemaking proceeding pursuant to section 406 that would have set tolerances for approximately 100 different pesticides. *1953 Pesticide Hearing* 121. However, due to the number of substances and parties involved, the volume of data compiled, and the vast agency resources required, none of the tolerances had been issued by 1953. As a result, food producers were uncertain of how much of these substances they could use on their crops without violating the law, and the public was afraid to eat products that had been sprayed with these toxic substances. 100 Cong. Rec. 153 (1954)(remarks of Rep. Miller); H.R. Rep. No. 1385, *supra*, pp.

4-5. Thus, the industry, with the support of the FDA, requested that Congress amend the FDC Act to provide for a less time-consuming and less cumbersome procedure for setting tolerances for pesticides. Congress responded by passing the 1954 Pesticide Amendments, which take pesticides out of the rulemaking requirements of section 406, and instead direct the Secretary to set tolerances for pesticides under a different, more expeditious procedure. *See* FDC Act § 408, 21 U.S.C. § 346a.

This history of the Pesticide Amendments is instructive for a number of reasons. First, if, as the FDA contends, the agency may use action levels without complying with the rulemaking requirements of section 701(e), then in the early 1950's there would have been no reason for the FDA or the industry to seek relief from those requirements in their efforts to expedite the issuance of tolerances for pesticides. Thus, contrary to the FDA's suggestion that Congress knew of its use of informal tolerances and "did nothing to require its abandonment in favor of exclusive reliance on formal rulemaking" (Br. 42), Congress dealt with the problem by enacting a special statutory scheme for establishing tolerances for pesticides.

Second, the argument that Congress intended to sanction the FDA's use of action levels is further undercut by the fact that Congress specifically provided for a means of setting a "temporary tolerance" for pesticides that were being used experimentally. While it is true that Congress may have been aware that the FDA had used informal tolerances to regulate pesticides and other substances covered by section 406 (*see* Pet. Br. 40 n.41), it also recognized that "[t]here are no provisions for such exemptions or temporary tolerances in the present law." H.R. Rep. No. 1385, *supra*, p. 6. Therefore, Congress deemed it necessary to include section 408(j) to give the FDA explicit authority to issue temporary tolerances for experimental pesticides. Under that section, the Secretary may "establish a temporary tolerance for the pesticide chemical. . . whenever in his judgment such action is deemed necessary to protect the public health. . ." 21 U.S.C. § 346a(j). Surely, if the FDA already had a system for bypassing the formal rulemaking re-

quirements of section 406 which was consistent with the FDC Act, there would have been no need for Congress to amend the statute to include section 408.

Third, Congress responded to the specific problems raised with respect to pesticides (*i.e.*, the unanticipated increase in the number of new substances and the need to expedite the procedures for setting tolerances for them), by carving out a separate procedure for regulating pesticides, and not by changing the general scheme for regulating added contaminants under section 406. Thus, the FDA's suggestion (Br. 42) that Congress was generally critical of the formal rulemaking requirements of section 406 is belied by the fact that Congress left that section intact with respect to regulating all added contaminants other than pesticides.[12]

Finally, the history of the 1954 Pesticide Amendments demonstrates that if, as the FDA contends, there are similar policy arguments which would support excluding other contaminants from the formal rulemaking requirements of section 406, those arguments should be made to Congress. If Congress agrees, it can follow the example of the Pesticide Amendments and decide that the regulatory scheme in section 406 is no longer the best way to protect the public from unsafe contaminants in food. But until such time, the FDA must comply with the clear mandate of the FDC Act and allow public participation when establishing the allowable levels of substances such as aflatoxins.

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[12] That Congress intended the requirements of section 406 to continue to apply to all added substances, except pesticides, is demonstrated by the following exchange between Congressman O'Hara and a representative of the National Canners Association:

> *Congressman O'Hara:* This has nothing to do with—this proposed legislation has nothing in the way of an effect upon section 406 of the present law. This is true, is it not?
>
> *Mr. Austern* [on behalf of the National Canners Association]: That is true.

Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce, 83d Cong., 2d Sess. 32 (1954).

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed. If the Court reverses the judgment below, it should remand the case for a decision on whether the Administrative Procedure Act, 5 U.S.C. § 553, requires the FDA to provide an opportunity for notice and comment on its action levels.

Respectfully submitted,

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In the Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG,
COMMISSIONER OF FOOD AND DRUGS, PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

As we established in our opening brief, since the enactment of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, nearly 50 years ago, the Food and Drug Administration (FDA) has consistently construed the Act as allowing the agency to regulate the presence in food of necessary or unavoidable added contaminants, such as aflatoxin in corn, either by exercising its broad prosecutorial discretion to bring individual enforcement actions pursuant to Section 402(a)(1), 21 U.S.C. 342(a)(1), or by adopting regulations ("tolerances") via formal rulemaking pursuant to Sections 402(a)(2)(A) and 701(e), 21 U.S.C. 342(a)(2)(A) and 371(e). The agency's construction of these provisions is fully consistent with their overall structure and legislative history, with the role that they play in the enforcement process, and with this Court's understanding of their operation. See *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 161, 166-167 (1958). The FDA's longstanding regulatory practice has not compromised the public health or resulted in inadequate enforcement of the food adulteration provisions of the statute, and it has enabled the agency to allocate its scarce resources to matters of more urgent public concern. Congress has also been made aware of the agency's construction of the FDCA on several occasions during this

period and has neither criticized the agency nor required it to alter its regulatory practice. On the contrary, Congress has modified other sections of the FDCA in express reliance on the FDA's views. For these reasons, and because the court of appeals failed to give any deference to the views of the expert agency responsible for administering a complex regulatory scheme (see, *e.g.*, *United States* v. *Riverside Bayview Homes, Inc.*, No. 84-701 (Dec. 4, 1985), slip op. 9-10, 17; *Chemical Manufacturers Ass'n* v. *NRDC*, No. 83-1013 (Feb. 27, 1985), slip op. 8), it is our submission that the court of appeals misconstrued Section 406 of the FDCA.

1. For the most part, respondents' answer (Br. 18-20) to our argument is simply that the term "shall" in Section 406 should be given its literal, dictionary meaning and that Section 406 therefore requires the FDA to adopt tolerances for every necessary or unavoidable added contaminant. That argument fails for several reasons.

a. First, as we explained in our opening brief (at 24-25), the construction of Section 406 adopted by the court of appeals renders the general food adulteration standard in Section 402(a)(1) wholly superfluous for added contaminants such as aflatoxin, even though the text of Section 402(a)(1) shows that it applies to such added substances.[1] Respondents attempt to

[1] Nor is the court of appeals' construction of Section 406 compelled by the text of that section when it is read as a whole. Respondents agree (Br. 18) that the phrase "to such extent as [the Commissioner] finds necessary for the protection of public health" would authorize, rather than require, the FDA to adopt tolerances if that phrase were adjacent to the verb "shall." However, the eight words separating these terms in Section 406 can scarcely be taken as manifesting a congressional intent wholly to preclude any effect of the former upon the latter. The origin of the "to such extent" clause makes this point. That clause was included in the bill that became the FDCA when the text of the bill provided that the FDA was "authorized" to issue tolerances. See Amicus Nat'l Food Processors Ass'n Br. App. 5a comment. The "to such extent" clause was thus clearly intended to guide the FDA's decision *whether* to set a tolerance, not the decision what particular tolerance level should be set.

Moreover, respondents' claim (Br. 30 n.7) that the "to such extent" clause "was included to describe the standard for setting tolerances" is inconsistent with the final sentence of Section 406, which explicity prescribes the factors to be taken into account in determining the quantity of the substance to be tolerated. Only the "to such extent" clause served or could serve to established a standard for deciding *whether* a tolerance should be adopted at all. If Congress intended the "to such extent" clause as nothing more than a limitation on the tolerance level set by the agency, as respondents contend, then logic would have dictated that it should have been placed in the final sentence of Section 406 along with the factors that the agency is expressly directed to "take into account" in "determining the quantity of such added substance to be tolerated."

avert this result by partially abandoning the construction of Section 406 that they championed in the court of appeals. There, respondents argued that a food was adulterated if it contained any amount of a necessary or an unavoidable added contaminant and no tolerance was in effect (see Resp. Br. 23 n.5),[2] and the court of appeals agreed.[3] Respondents have now forsaken that argument and agree with our position that food containing such a substance is adulterated only if a tolerance is in effect and the food contains that contaminant in an amount exceeding the tolerance. Respondents insist (Br. 20-22) that their new reading of Section 406 does not render Section 402 (a)(1) superfluous, because it can function as a transitional device until a tolerance has been adopted. However, respondents' argument suffers from much the same flaw as the court of appeals' reading of Section 406.

The only material difference between the interpretation of Section 406 that was adopted by the court of appeals and the one that is now offered by respondents is simply a matter of timing. Whereas the court of appeals' construction of Section 406 renders Section 402(a)(1) superfluous today, respondents' construction of Section 406 renders Section 402(a)(1) super-

[2] See also Plaintiffs-Appellants C.A. Br. 14, 19, 21; Plaintiffs-Appellants C.A. Reply Br. 3-4.

[3] Although they now agree with our construction of Section 406 on this point, respondents assert (Br. 23) that the court of appeals did not conclude that the absence of a tolerance automatically renders a food adulterated if it contains any quantity of a necessary or an unavoidable added contaminant. However, the court of appeals' opinion shows that respondents are wrong. See, *e.g.*, Pet. App. 7a ("[s]ince the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce"); *id.* at 4a, 15a.

fluous at some unknown day in the future. Respondents admit (Br. 12-13, 21-22) that, once the FDA adopts tolerances for necessary or unavoidable added contaminants, Section 402(a)(1) will have no role to play in their regulation. There is no evidence, however, that Congress intended the general adulteration standard in Section 402(a)(1) to be replaced by tolerances in every case or, in general, to have a half-life as respondents claim. Respondents' construction of the Act should therefore be rejected.

There was also no reason for Congress to have intended Section 402(a)(1) to function as a transitional provision. Congress has historically included transitional provisions in the FDCA only when it has enacted amendments providing that regulated articles may not be marketed in interstate commerce without a license from the FDA. For example, Congress added a transitional provision to the Color Additives Amendment of 1960, Pub. L. No. 86-618, § 203, 74 Stat. 404-407, because the amendment prohibited the use of color additives in food in the absence of a license. A transitional mechanism was therefore necessary to allow food containing previously used additives to be marketed until a food producer had the opportunity to obtain a license for the additive. But, as we have shown (Pet. Br. 20-23, 34-35) and as respondents now agree (Br. 22-23), a food containing an added contaminant (such as aflatoxin) is *not* adulterated if there is no tolerance in effect, *i.e.*, if there is no "license." That food can be marketed before a tolerance is adopted. Thus, it would have been pointless for Congress to have included a transitional provision for added food contaminants in the FDCA. Put another way, because Section 406 is not a licensing provision, it makes no sense to treat Section 402(a)(1) as a transitional provision.

To be sure, the FDA could rely on Section 402(a)(1) as a transitional device (albeit with the practical difficulties noted below) if the judgment below were affirmed. The relevant question, however, is not whether Section 402(a)(1) *could* serve this function, but is whether it was *intended to* or *must* fill *only* that function. Nothing in its text or legislative history suggests that it should be so limited. Furthermore, limiting the usefulness of Section 402(a)(1) in the manner that respondents suggest is inconsistent with this Court's decision in *Flemming* v. *Florida Citrus Exhange, supra,* which recognized that Congress intended to allow the FDA to rely on Section 402(a)(1) to enforce the food adulteration provisions of the FDCA on a case-by-case basis. See 358 U.S. at 166; Pet. Br. 34-35. Finally, as we pointed out in our opening brief (at 25), treating Section 402(a)(1) as a transitional provision will lead to considerable practical difficulties in the enforcement of the FDCA because Sections 406 and 402(a)(1) do not define the length of any transitional period or specify any factors for the courts to consider in deciding when it will expire. Respondents have failed to explain why their new reading of Section 406 will not simply invite needless litigation over this issue.[4]

b. In relying on the dictionary definition of the term "shall," respondents forget that Congress drafted the FDCA to function "as a working instrument of government and not merely as a collection of English words." *United States* v. *Dotterweich,* 320 U.S. 277, 280 (1943). Here, the legislative history of the FDCA clearly shows that Congress and the FDA both construed Section 406 as granting the agency the authority to set tolerances, not as requiring the agency to do so.

First, the original version of the FDCA (S. 1944, 73d Cong., 1st Sess. § 10(a) (1933)), which was drafted by the agency, also contained the verb "shall" that is found in the current version of Section 406. During the hearing on the bill, Walter Campbell, Chief of the FDA, repeatedly stated that the agency drafted this provision to supplement its enforcement authority under existing law by obtaining the discretionary authority to adopt

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[4] In fact, litigation over this question has already begun. In *National Wildlife Federation* v. *Bowen,* petition for review, No. 85-3943 (6th Cir. filed Nov. 11, 1985), the National Wildlife Federation, relying solely on the court of appeals' decision in this case, has asked the court of appeals to order the FDA to set a tolerance for dioxin in fish and other classes of food. If the court of appeals' decision here is upheld, it is reasonable to expect a spate of litigation along this line in which parties who are disappointed by the agency's failure to adopt a tolerance will claim that the FDA is required to issue one under Section 406 whenever it is asked to do so.

tolerances. Pet. Br. 28 & n.24.[5] Senator Copeland, whose views, as sponsor of that bill, offer an authoritative guide to its meaning (see *Grove City College* v. *Bell*, 465 U.S. 555, 567 (1984)), also read this section as empowering, not requiring, the FDA to establish tolerances. Pet. Br. 29. Plainly, neither of the principal architects of the bill believed that the dictionary meaning of the term "shall" was of any significance.

Congress also shared the agency's interpretation. The various bills considered as replacements for the Federal Food and Drugs Act of 1906, 21 U.S.C. (1928 ed.) 1 *et seq.*, used the terms "shall" and "is authorized to" interchangeably, but every committee report stated that the FDA would be authorized to set tolerances, regardless of the actual terms used by these bills. Pet. Br. 29-30 & nn.29-31. And at no time during the five-year period that the FDCA was under consideration did anyone suggest that the FDA should be required to adopt tolerances. Given this clear, oft-stated, and unwavering expression of Congress's and the agency's intent, their understanding of the term "shall," not Webster's, is dispositive.[6]

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[5] Respondents' quotation (Br. 27) from FDA Chief Campbell's testimony at the Senate committee hearing is seriously misleading. The eight words quoted by respondents come from his exchange with Senator Copeland in which he explained that the FDA sought the authority to adopt pesticide tolerances because they were the primary menace to public health. *Foods, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 25-26 (1933) [hereinafter cited as *1933 S. 1944 Hearings*]. Read as a whole, Campbell's testimony shows that he read Section 10(a) of S. 1944 as granting the agency discretionary authority to set tolerances. *1933 S. 1944 Hearings* 18-26, 80-81; Pet. Br. 28 & nn.24-25.

[6] Respondents find it "iron[ic]" (Br. 25) that, given the FDA's oft-stated request to be granted the authority to adopt tolerances, the agency has infrequently relied upon Section 406 since it was enacted. Respondents suggest (Br. 25) that the FDA has declined to adopt tolerances simply to "lessen the burdens" that the tolerance-setting process would impose on the agency. We agree with respondents that the tolerance setting process is quite burdensome (Pet. Br. 6-7, 45-47), but respondents err in suggesting that the agency has refused to carry out an express congressional directive simply to avoid the burden of formal rulemaking. The FDA has long found that case-by-case litigation fully protects the public health, and respondents do not claim that the agency's historic regulatory practice has jeopardized the public health in any respect. Moreover, history shows that respondents' criticism is unfounded

c. Equally important, however, is that respondents' account of the provenance of the term "shall" is *Hamlet* without the Prince of Denmark. Respondents have failed to offer any reasoned explanation why Congress would have sought to deprive the FDA of the discretion to select between the alternative methods of enforcing the food adulteration provisions set forth in Sections 402(a)(1) and 406 by requiring the FDA to adopt tolerances. Respondents do not suggest that Congress found that the FDA had inadequately enforced the adulteration provisions of the 1906 Act or that exclusive reliance on tolerances was the preferred way to protect the public health. The legislative history of the FDCA also discloses no criticism or finding of this type. Pet. Br. 30-31. In fact, the only criticisms of the FDA were voiced by the apple industry, which feared that the FDA would be too aggressive in its efforts to enforce the Act. Pet. Br. 31-32. And Congress incorporated into the FDCA the section in the 1906 Act that empowered the FDA to act on a case-by-case basis (see *Flemming*, 358 U.S. at 161; Pet. Br. 34-35), which shows that Congress did not forbid this regulatory approach.

Instead, respondents argue that Congress required the FDA to adopt tolerances in order to ensure "public participation" in the enforcement process. Br. (i), 2, 8, 14, 15, 35, 38. However, respondents' repeated references to Congress's asserted intent are not supported by a single reference to the legislative history of the Act. In fact, that history plainly shows that the administrative procedures found in Section 701(e) were added at the request of the apple industry to ensure that food producers, not consumers, would be able to participate in the tolerance-setting process. Moreover, these procedures were adopted not

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for another reason as well. Section 406 was adopted primarily to deal with the problem of pesticide residues in foods (Pet. Br. 17-18 n.14, 27 & n.21, 31-33) and, after a period during World War II, when the FDA's resources were diverted to other matters, the FDA adopted a tolerance for fluorine in 1944 (*id.* at 46 n.46). Once the Act of July 22, 1954 (the Pesticide Chemicals Amendment of 1954), 21 U.S.C. 346a, was adopted, there was no need to resort to Section 406 to adopt tolerances for pesticides. Most unavoidable added contaminants, such as aflatoxin, were not discovered until the 1960's. Pet. Br. 47-48 n.49. Respondents' criticism thus overlooks the historical context of the FDA's use of tolerances.

to require the FDA to set tolerances, but simply to ensure that the apple industry would be able to participate if the FDA decided to do so. Pet. Br. 31-34. Respondents' failure to explain why Congress would have intended to restrict the FDA's enforcement discretion is powerful evidence that Congress had no such intent in the first place. Indeed, because there is no evidence that Congress intended to restrict the FDA's discretion to enforce tolerances once they have been adopted (cf. *Heckler* v. *Chaney*, No. 83-1878 (Mar. 20, 1985), slip op. 13-14), respondents' contention that Congress was concerned with public participation in the enforcement process is dubious on its face. And to the extent that respondents' construction of Section 406 is an attempt to place a contemporary gloss on a 1938 statute, their argument should be presented to Congress, not to this Court. See *Potomac Electric Power Co.* v. *Director, OWCP*, 449 U.S. 268, 280 (1980).[7]

2. Respondents also argue (Br. 26-31) that the legislative history of the FDCA is consistent with their construction of the text of Section 406. Respondents rely almost exclusively on two aspects of that history: (a) the fact that the House replaced the phrase "is authorized to" in the final Senate version of the FDCA with the term "shall," and (b) the fact that the House made the identical substitution in four other sections of the Senate bill. Neither argument has merit.

a. The House amendment to Section 406 is not significant in this case because the House Report and the floor debate show that the House intended Section 406 to authorize, not require, the FDA to establish tolerances. The House Report expressly stated that Section 406 "authorized" the FDA to adopt tolerances (H.R. Rep. 2139, 75th Cong., 3d Sess. 6 (1938)), and the explanatory remarks made during the floor debate on the House amendment by supporters and opponents of the amend-

[7] Section 701(e) does provide that the issuance, amendment, or repeal of a tolerance can be initiated by a proposal offered by the FDA or by a petition, "showing reasonable grounds therefor," filed by any interested person with the FDA. However, respondents never petitioned the FDA to set a tolerance for aflatoxin in corn or in any other food.

ment alike make the same point (Pet. Br. 33 & n. 35).[8] To be sure, the House Report does not explain why the House decided to modify the verb in the Senate bill. But respondents err in claiming that "[a]ll that is known" is that the House modified the Senate bill (Br. 28); the House Report and the floor debate demonstrate that the House did not intend its amendment to have a substantive effect. Thus, by itself the fact that the House modified the Senate version of Section 406 is of no consequence in this case.

Respondents attempt to explain away these direct and unequivocal statements of contrary congressional intent by contending (Br. 29) that they are "consistent with respondents' interpretation and the literal language of the statute." However, respondents are mistaken. Their argument (Br. 29) that "the

[8] The following excerpt from the House debate is illustrative (83 Cong. Rec. 7774 (1938) (emphasis added)):

> Mr. LEA: * * * The addition of poison to foods is prohibited except where such addition is necessary or cannot be avoided; and in such cases tolerances are provided limiting the amount of added poison to the extent necessary to safeguard the public health.
>
> At this point I call attention to the question discussed a while ago as [to] spray residue on fruit. *This bill provides that the Secretary of Agriculture shall have authority after proper hearing to prescribe the extent of spray residue that shall be permissible.* Then the regulation is enforceable. There is nothing in this bill that fails to protect the public health against spray residue. *In the present law there is no such authority in the Secretary of Agriculture. The only method of prosecuting in connection with that condition at the present time is to treat spray residue as an adulteration.*
>
> * * * * *
>
> Mr. SIROVICH: Is there anything in this measure which would compel the Government of the United States to insist upon the washing off of the toxic residue that may be found upon fruits and vegetables?
>
> Mr. LEA: The only way of handling that situation at the present time is for the Secretary to say, in effect, that if he finds more than a certain amount of spray residue, he will prosecute criminally for adulteration. *There is no authority by which he can legally adopt regulations. He must resort to the criminal procedure for adulteration. If enacted, this bill would give him the right after proper hearings to adopt regulations prescribing limits.* Then a court review would be permitted, and if the interested parties claimed the regulation was invalid, they would have the right to go into court and have that question considered.

principal focus of attention by everyone, including the FDA, was in creating this new [tolerance-setting] authority" in Section 406 is unsupported by anything in the legislative history. As we have explained in detail (Pet. Br. 28-34), Section 701 was the only subject of controversy (or even debate), not Section 406. From the outset, Congress acceded to the FDA's request that it be empowered to adopt tolerances as an additional enforcement tool to be used in the agency's discretion; the only controversy stemmed from the procedures that the agency proposed to adopt tolerances, not from its request for the discretionary authority to do so.[9]

Respondents' analysis of the legislative history is also premised on a misconception of the differences between action levels and tolerances. Respondents repeatedly assert that action levels are the same as tolerances.[10] Respondents then conclude (Br. 29-30) that, by requiring the FDA to follow the procedures set forth in Section 701(e) to set a tolerance, Congress prohibited the agency from relying on action levels to regulate the presence in food of any added contaminant for which the FDA could adopt a tolerance. However, respondents' premise is seriously flawed.

As we have explained (Pet. Br. 3, 5-6, 27-28), the FDA's action levels are, and have always been, informal and internal prosecutorial guidelines.[11] Contrary to respondents' assertions,

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[9] Indeed, respondents' analysis of the legislative history is self-defeating in this regard. If Section 406 truly were the "principal focus of attention," the House Report and the floor debate would take on heightened importance.

[10] For instance, respondents state that " 'action levels' have the same legal effect as a regulation issued under section 701(e) [*i.e.*, a tolerance]" (Br. 2), that a "tolerance operates like a license for food producers" (Br. 7), that action levels and tolerances "confer[] precisely the same benefits on food producers" (Br. 7), that "an action level binds the agency from proceeding against food producers" (Br. 12), that "action levels * * * authorize added poisonous and deleterious substances in food" (Br. 25); and that FDA's pre-1938 action levels, which the FDA termed, for want of a better name, "administrative tolerances" (*1933 S. 1944 Hearings* 22 (FDA Chief Campbell)), "amounted to a license to market foods as long as the contaminants were below the tolerance level" (Br. 27).

[11] Respondents also insist (Br. 5) that food containing any amount of aflatoxin is adulterated because there is no known safe level of aflatoxin contamination. However, that claim is both legally and factually erroneous. As a legal matter, since there is no tolerance in effect for aflatoxin, the FDA must prove under Section 402(a)(1) that food containing aflatoxin may "render [the food] injurious to health" (21 U.S.C. 342(a)(1)). See *Fleming*, 358 U.S. at 161; *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914); Pet. Br. 4. The issue is not whether the substance itself (or the food) has been proven to be safe. As a factual matter, the evidence shows that food must contain 20 parts per billion (ppb) of aflatoxin in order for it to present any reasonable possibility of harm. J.A. 188, 193, 194, 225. For certain uses, moreover, corn must contain more than 100 ppb aflatoxin before it may become injurious to health. Pet. Br. 9-10 n.10. The FDA's current 20 ppb action level for aflatoxin therefore does not represent any largesse on the part of the agency, as respondents suggest (Br. 7, 9, 12, 32). Rather, the action level represents the level of contamination at which the FDA has the evidence of a reasonable possibility of injury that is necessary to prove adulteration under Section 402(a)(1). Pet. Br. 8-9.

action levels do not "authorize" food producers to do anything.[12] Nor does a violation of an action level render a food per se adulterated; on the contrary, the FDA must prove in court in each case that a particular contaminated food may be injurious to health. By contrast, tolerances have the force and effect of law. Once a tolerance is set, food containing a contaminant in an amount below the tolerance level is not adulterated, but a violation of a tolerance does render a food per se adulterated. Thus, given the critical differences between these alternative enforcement mechanisms, the fact that Congress required the FDA to follow specific procedures to adopt a tolerance does not, by negative implication, suggest that Con-

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[12] Respondents also erroneously claim (Br. 7) that, so long as the level of a contaminant does not exceed the amount that is "authorized" by an action level, "food producers receive full protection from FDA enforcement actions." Action levels are similar to FDA advisory opinions (see 21 C.F.R. 10.85) or guidelines (see 21 C.F.R. 10.90), and the FDA's regulations explicitly state that, in unusual situations involving an immediate and significant danger to public health, the agency may take appropriate civil enforcement action contrary to an advisory opinion (21 C.F.R. 10.85(f)) or a guideline (21 C.F.R. 10.90(b)(3)) before it is revoked or amended. Cf. *McIlwain* v. *Hayes*, 530 F. Supp. 973, 977-978 n.8 (D.D.C. 1981), aff'd, 690 F.2d 1041 (D.C. Cir. 1982) (FDA not bound in court by advisory opinions). Accordingly, if the FDA were to conclude that its 20 ppb action level for aflatoxin presented a danger to the public health, the agency has the authority to take immediate action before that action level is modified.

gress also prohibited the agency from relying on action levels. Respondents' argument falls with its premise.

b. Respondents also rely (Br. 19-20, 30) on the fact that the House replaced the term "is authorized to" in the Senate bill with the verb "shall" in four other places in the FDCA, Sections 401, 406(b), 501(b), and 604. But here, too, the House Report shows that these amendments were not substantive, because it spoke in terms of granting the FDA the "authority" to act. H.R. Rep. 2139, *supra*, at 5, 6, 9.[13] Indeed, respondents concede as much (Br. 30). In fact, this Court read one of these sections in precisely that way in *Federal Security Adm'r* v. *Quaker Oats Co.*, 318 U.S. 218, 230 (1943) (emphasis added; citation omitted), stating that "it was the purpose [of Section 401] to *authorize* the Administrator to promulgate definitions and standards of identity 'under which the integrity of food products can be effectively maintained.' " See also *id.* at 232 (emphasis added) ("[t]he statute accomplished that purpose [of providing consumers with information] by *authorizing* the Administrator to adopt a definition of identity * * *").[14] Accordingly, these amendments prove our point, not respondents', because they demonstrate that the House saw no difference between the terms "is authorized to" and "shall."

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[13] *Id.* at 5 ("Section 401 provides much needed authority for the establishment of definitions and standards of identity and reasonable standards of quality and fill of container for food"; noting that the bill "authoriz[es] the establishment of definitions and standards of identity"); *id.* at 6 ("Subsection (b) of this section [*i.e.*, 406] specifically authorizes the listing of harmless coal-tar colors for use in food and the certification of batches of the listed colors which are found to be sufficiently free from impurities to be safe"); *id.* at 9 ("Section 604 authorizes certification of coal-tar colors for cosmetics and is similar to sections on this subject provided with respect to foods and drugs"). The House Report does not use the term "authorize" in connection with Section 501(b), 21 U.S.C. 351(b) (see H.R. Rep. 2139, *supra*, at 6-7), but the FDA has also never construed this subsection as being mandatory.

[14] Respondents suggest (Br. 19-20) that the Court's decision in *Quaker Oats* construed Section 401 as requiring the FDA to adopt food identification standards, but the opinion will not bear that reading. The question in *Quaker Oats* was whether certain such standards were supported by substantial evidence, and the passages from the Court's opinion that are quoted by respondents came during the course of the Court's discussion of the factors that the agency must take into account when it adopts a food identity standard. See 318 U.S. at 227-228. Properly read, these passages mean only that the FDA must consider the statutory factors when it decides to adopt food identity standards. In addition, the passages quoted above in the text show that the Court did not construe Section 401 as respondents suggest.

3. We explained in our opening brief (at 39-43) that the FDA brought its interpretation of Section 406 to Congress's attention on three separate occasions when Congress considered revisions to the Act—in 1954, when Congress adopted the Pesticide Chemicals Amendment, 21 U.S.C. 346a; in 1958, when Congress adopted the Food Additives Amendment, Pub. L. No. 85-929, 72 Stat. 1784 *et seq.*; and in 1960, when Congress adopted the Color Additive Amendments, Pub. L. No. 86-618, 74 Stat. 397 *et seq.* At no time did Congress criticize the FDA's regulatory practice or require the agency to alter it, and Congress relied on the FDA's construction in adopting the 1954 amendment. Whatever doubts there may be in other contexts of the strength of subsequent legislative history such as this, here these amendments show that the FDA has correctly discerned Congress's intent. See *Bob Jones University* v. *United States*, 461 U.S. 574, 601-602 (1983); *United States* v. *Rutherford*, 442 U.S. 544, 554 & n.10 (1979).[15]

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[15] Respondents' argument (Br. 24) that the FDA's construction of Section 406 is neither longstanding nor consistent borders on the frivolous. The FDA first stated its position in 1933 when the agency drafted and submitted to Congress the bill that ultimately became the FDCA and when FDA Chief Walter Campbell testified before a congressional committee (Pet. Br. 28-29); the FDA publicly announced its position in trade correspondence issued in the 1940's shortly after the FDCA was adopted (*id.* at 17 n.14, 37 n.38); the FDA expressly brought its position to Congress's attention on three occasions between 1953 and 1960 (*id.* at 40 n.41, 42 n.42); and the FDA's position is reflected in its current regulations, which were adopted in the 1970's (*id.* at 37-38). That the FDA did not set tolerances for food contaminants once the FDCA went into effect (*id.* at 36) also provides a " 'contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion, of making the parts work efficiently and smoothly while they are yet untried and new.' " *Udall* v. *Tallman*, 380 U.S. 1, 16 (1965) (citation omitted). Finally, since 1938 the FDA has regulated the presence of added contaminants in food primarily, albeit not exclusively, by relying on action levels in case-by-case litigation under Section 402(a)(1). Pet. Br. 3, 5-8, 43 & n.43.

Ignoring the last two occasions, respondents contend (Br. 35-38) that the legislative history of the Pesticide Chemicals Amendment of 1954 shows that Congress disapproved of the FDA's reliance on action levels. However, respondents' arguments are either beside the point or misconstrue that amendment.

a. Respondents' first argument (Br. 37) is that it would have been unnecessary for Congress to adopt a special tolerance-setting procedure for pesticides if the FDA could have regulated these substances by relying on informal action levels. However, here, too, respondents' argument ignores the critical differences between action levels and tolerances. The failure to comply with a pre-1954 pesticide action level did not constitute a per se violation of the FDCA any more than the failure to comply with the action level currently in force for aflatoxin amounts to a per se violation of the Act today. Only the failure to comply with a tolerance has that effect. Congress's decision in 1954 to adopt a streamlined procedure to set pesticide tolerances thus hardly signifies its disapproval of the FDA's prior reliance on action levels for pesticides, much less the agency's current reliance on action levels to regulate added contaminants that were not affected by that amendment.

b. Respondents similarly argue (Br. 37-38) that Congress disapproved the FDA's use of action levels because Congress, by enacting Section 408(j), 21 U.S.C. 346a(j), as part of the 1954 amendment, authorized the FDA to set a "temporary tolerance" for pesticides that are used on an experimental basis. It was unnecessary for Congress to do so, respondents claim, if the FDA could have achieved the same result by relying on action levels.

Here, too, respondents have confused action levels with tolerances, and their argument must be rejected for that reason alone. But respondents' argument is flawed for another reason as well. Congress adopted Section 408(j) in the 1954 Amendment because Sections 408(a) and 402(a)(2)(C) of that Amendment, 21 U.S.C. 346a(a) and 342(a)(2)(C), unlike Sections 406 and 402(a)(2)(A) of the FDCA, 21 U.S.C. 346 and 342(a)(2)(A), prohibit the addition to food of a pesticide unless (i) a pesticide tolerance is already in effect and the amount of that pesticide in the food is within the tolerance limits, or (ii) the pesticide has

been exempted from this requirement. In other words, because a pesticide cannot be used in food in the absence of a tolerance or an exemption, it was necessary for Congress to adopt Section 408(j) in order to authorize the FDA to set temporary tolerances providing for the experimental use of pesticides. Therefore, Congress did not adopt Section 408(j) to prohibit the FDA from relying on action levels or because Congress disapproved that practice. Rather, Congress adopted the temporary tolerance provision of Section 408(j) for reasons that are peculiar to the new system for regulating pesticides.

c. Finally, relying on the fact that Congress responded to the specific problems presented by pesticides by carving out a separate procedure for their regulation and not by changing the general scheme for regulating added contaminants under Section 406, respondents challenge (Br. 38) our argument that Congress was critical of the formal rulemaking requirements of Section 701(e), 21 U.S.C. 371(e), that are necessary to set tolerances. However, our argument was based upon (Pet. Br. 41-42, 46-47) the clear and unequivocal criticisms stated in the Senate and House Reports of the then-existing tolerance-setting procedures in Section 701(e). These criticisms speak for themselves and provide a complete answer to respondents' argument. Respondents concede (Br. 37) that the 1954 Amendment was enacted to establish a less time-consuming and less cumbersome tolerance-setting procedure for pesticides than the one prescribed by Section 701(e). That Congress did not also alter the procedural requirements imposed by Section 701(e) for the added substances that remained within the scope of Section 406 is beside the point, which is that Congress endorsed the FDA's construction and implementation of Sections 406 and 402(a)(1) when it enacted the 1954 Amendment. Only if the FDA wished to establish tolerances under Section 406 by informal rulemaking would the agency have needed to persuade Congress to amend the procedural requirements of Section 701(e) insofar as they apply to Section 406, or to amend Section 406 to exclude from its scope added contaminants other than pesticides. Respondents' argument is simply not responsive to our point.

4. Finally, respondents argue (Br. 31-35) that the FDA has overstated the adverse effects of the court of appeals' decision. Respondents discount (Br. 32-33) the risk that tolerances will hamper the agency's ability to respond to new toxicological data or changes in manufacturing practices by asserting that the FDA has never lowered its action levels in response to an emergency and by arguing that the formal rulemaking requirements will not retard the agency's ability to respond to an emergency should one develop. However, respondents' assertions are factually wrong, as the FDA's experience with polybrominated and polychlorinated biphenyl contamination reveals.[16] More importantly, the agency can hardly be criticized for its unwillingness to risk the public health by assuming that no emergencies will occur. Finally, any interpretation of the FDCA that requires the agency to take risks of this type is inconsistent with the principle that the Act should be liberally construed to protect the public health. See *United States* v. *An Article of Drug * * * Bacto Unidisk*, 394 U.S. 784, 798 (1969).

Respondents maintain (Br. 34) that their construction of the Act will not burden the FDA. For instance, they suggest that FDA can lessen the burden of formal rulemaking by relying on the summary judgment procedures upheld in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973), in the

[16] In May and June 1974, following the discovery of the blending of polybrominated biphenyls (PBBs) and animal feed that resulted in the contamination of Michigan dairy cattle, the FDA established action levels of 1.0 parts per million (ppm) for PBBs in milk and meat fat, 0.1 ppm for PPBs in eggs, and 0.3 ppm for PBBs in animal feed. In November 1974, following a more detailed review of PBB toxicity, including toxicity studies conducted by its Bureau of Foods, as well as advances in the analytical methods for detecting the presence of PBBs in foods and feeds, the FDA lowered the action levels to 0.3 ppm for PBBs in milk and meat fat, 0.05 ppm for PBBs in eggs, and 0.05 ppm for PBBs in feed. See *Toxic Substances: Hearings on Polybrominated Biphenyl Contamination in Michigan Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation*, 95th Cong., 1st Sess. Pt. 2, at 954, 968-971, 1007-1011, 1028, 1046, 1057, 1417 (1977). Had a tolerance been in effect for PBBs in foods and feeds, the FDA would not have been able to respond nearly as quickly to the new toxicological data, as demonstrated by the agency's experience in attempting to lower the tolerance for polychlorinated biphenyls in food (Pet. Br. 45 n.45).

context of new drug applications. But, as we have explained (Pet. Br. 46-47 n.47), there is no reason to presume that such a procedure will substantially reduce the burdens imposed by formal rulemaking, or will not lead to unnecessary litigation over this question. Respondents also argue (Br. 35) that setting tolerances is a more efficient way to protect the public health than case-by-case litigation. But the question of how best to regulate contaminants such as aflatoxin involves precisely the type of scientific and policy judgments that Congress has entrusted the FDA to make. See *Chaney*, slip op. 10; *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411, 413 (1958) ("the Commission alone is empowered to develop that enforcement policy best calculated to achieve the ends contemplated by Congress and to allocate its available funds and personnel in such a way as to exercise its policy efficiently and economically").

At bottom, respondents misconstrue the significance of our reliance on these so-called "policy considerations" (Br. 31). We do not contend that the FDA may dispense with the burden of setting tolerances through formal rulemaking requirements if Congress in fact required the agency to regulate in that manner. Rather, our submission is that the agency has long concluded that in many circumstances the costs of adopting tolerances outweigh their benefits, there is no evidence that Congress disagrees with the agency, and, accordingly, there is no good reason to construe the FDCA in a manner that requires the agency to abandon its longstanding and successful regulatory practice.

For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

FRANK YOUNG,
Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF AMICUS CURIAE NATIONAL FOOD PROCESSORS ASSOCIATION

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

No. 85-664

FRANK YOUNG,
Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF AMICUS CURIAE NATIONAL FOOD PROCESSORS ASSOCIATION

INTEREST OF AMICUS CURIAE

Amicus submits this brief in support of the petitioner Frank Young, Commissioner of Food and Drugs. Consent to file this brief has been obtained from counsel for all parties and has been filed with the Clerk of this Court.

The National Food Processors Association ("NFPA") is a scientifically based trade association representing almost 600 member-companies that pack a broad range of processed-prepared food products for distribution throughout the country and the world. A substantial portion of these pro-

cessed products are prepared from fruits, vegetables, and other raw agricultural commodities which in their growing state are exposed to unintended and unavoidable contaminants in the natural environment and which thereby contain extremely small but detectable levels of any number of such environmental contaminants that generally cannot be removed by processing operations. The detection, identification, and possible reduction of these environmental contaminants in raw and processed foods has for many years been an important aspect of the work carried on in the three scientific laboratories of NFPA.[1]

The food processor members of NFPA and the Association itself would thus be very substantially affected by an interpretation of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§ 301-392 (1982) ("the Act") that regards as adulterated all foods containing detectable amounts of any unavoidable environmental contaminant unless and until a formal tolerance has been established for each such contaminant in a broad range of agricultural commodities pursuant to costly, burdensome, and time-consuming evidentiary hearing procedures.

[1]The Association was founded in 1907 as the National Canners Association, growing out of the collective canning industry support for enactment of the Food and Drug Act of 1906. Since its first scientific research laboratory was opened in 1913 the Association has been actively involved in research, testing and training programs that contribute significantly to the safety of the food supply. The Association has continuously maintained its interest in food safety legislation and regulatory programs, including the Federal Food, Drug, and Cosmetic Act of 1938 and subsequent amendments. *See, e.g.*, the references to the involvement of the Association in the 1954 pesticide amendments to the Act, cited in the Government's Petition (Pet. 11-12 n.5).

SUMMARY OF ARGUMENT

Almost fifty years after the enactment of the Federal Food, Drug, and Cosmetic Act of 1938 a panel of the United States Court of Appeals for the District of Columbia Circuit has announced an unprecedented interpretation of key provisions of the Act that renders a substantial portion of the American food supply adulterated and unlawful, that makes it realistically impossible for growers and food company officials to heed this Court's admonition to "insure that violations [of the Act] will not occur,"[2] and that imposes a staggering burden on the FDA to initiate and complete formal evidentiary hearings for all unavoidable contaminants in hundreds of agricultural commodities. In holding that "the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulaterated,"[3] the court rejected the agency's contemporanous, consistent, and long-standing interpretation of the Act, and in so doing cited *no* judicial, legislative, administrative, or other authority that has *ever* interpreted the Act in this manner.

The sole basis for the court's conclusion was its reading of the provision in § 406 that "the Secretary shall promulgate regulations limiting the quantity [of unavoidable or required addded poisonous or deleterious substances in food] to such extent as he finds necessary for the protection of public health."[4] Because the court interpreted the "to such extent" clause as not modifying "the pivotal word 'shall'," it concluded that the Secretary "must" promulgate regulations embodying tolerances.[5] Although the court

[2]United States v. Park, 421 U.S. 658, 672 (1975).

[3]Pet. App. 15a.

[4]21 U.S.C. § 346.

[5]Pet. App. 7a.

purported to rely upon "the clear language of the statute," its decision has the effect of writing into § 406 a safety standard for environmental contaminants, and of rendering the key adulteration standard of § 402(a)(1) totally inoperative.

In rejecting the FDA's consistent interpretation of that statutory language in favor of its own, the court found it necessary to characterize legislative history supporting the FDA's interpretation as inconclusive and to dismiss all of the relevant cases on the ground that they "do not speak to the issue at hand."[6] The opinion makes no reference to the FDA's legal and policy analysis that accompanied the agency's promulgation of the regulations under which it adopted the aflatoxin action levels at issue.

In short, the court of appeals decision hangs solely by the thread of its selective and unprecedented reading of the statutory language. We respectfully submit that the court has misread the statutory language, disregarded the statutory purpose and scheme, misunderstood the legislative history and Congressional intent, and failed to reconcile its reading of the Act with the unambiguous dictates of this Court in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914), and *United States v. Park*, 421 U.S. 658 (1975).

[6]Pet. App. 15a.

ARGUMENT

I. THE LANGUAGE OF THE STATUTE DOES NOT SUPPORT THE HOLDING OF THE COURT BELOW THAT A SECTION 406 TOLERANCE MUST BE ESTABLISHED "IF FOOD WITH AN UNAVOIDABLE POISONOUS OR DELETERIOUS SUBSTANCE IS TO BE CONSIDERED UNADULTERATED"

The conclusion and holding of the court of appeals is succinctly stated in Part III of its opinion (Pet. App. 15a):

> [T]he FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1) or unsafe [sic] for purposes of 21 U.S.C. § 342(a)(2)(A), ...

This conclusion was said by the court to be based on "the language of the statute itself," which in the court's view "plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." Pet. App. 6a, 7a, 8a. On this basis the court held that "the FDA may not proceed by means of action levels rather than tolerances." Pet. App. 2a.

The court's interpretation of the "language of the statute" in § 402(a)(1), § 402(a)(2)(A), and § 406 – the operative language of which has remained essentially unchanged since enactment in 1938 – is in fact totally at odds with the wording of the statute and with the authoritative understanding and application of the statute for almost fifty years.

A. The First Clause of Section 402(a)(1) Embodies A Quantitative Rather Than An Absolute Standard of Adulteration For Added Poisonous or Deleterious Substances In Food

The beginning point is the first clause of § 402(a)(1), which provides that a food shall be deemed to be adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health." Though written in the broadest terms, this clause in fact applies only to poisonous or delterious substances that are "added" to food. The second clause of § 402(a)(1) provides that if a subtance is not "added" to but occurs naturally in food then the food is not considered adulterated if the quantity of the substance in the food "does not ordinarily render it injurious to health." That is a separate and more lenient standard than the standard of the first clause. This Court has held that, though more stringent, the adulteration standard of the first clause is not absolute: food is adulterated only if an added poisonous or deleterious substance is present in such quantity that it might render the food injurious to health. *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914); *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 161 (1958).

The court below plainly did not understand the centrality of the first clause of § 402(a)(1) in defining what substances added to food result in adulteration of the food. Its opinion wavers between recognizing the relevance of its own version of the first clause and ignoring it altogether. After quoting §§ 402(a)(2)(A) and 406 at the outset of Part I of the opinion as if they alone governed the adulteration of food because of the presence of added substances, the court stated in a seeming allusion to § 402(a)(1):

> Not only is it undisputed that aflatoxin is "poisonous or deleterious" and that it is an "added" substance, but the Secretary also admits facts, *see* Appellee's Brief at 4, sufficient to conclude that the presence of aflatoxin in food *may render such consumables injurious to health.* Hence, *section 342* [§ 402] would, except for the saving grace of section 346 [§ 406], *define any aflatoxin-tainted corn to be adulterated,* and such corn would therefore be banned from interstate commerce, *see* 21 U.S.C. 331(a).[7]

Standing alone, this brief passage may suggest that the court relied significantly on the Secretary's purported factual admission that any amount of aflatoxin "may render [food] injurious to health." But there was no such admission. The Government indeed "admits facts" at the cited page in the brief that support the conclusion that aflatoxin is poisonous or deleterious,[8] but neither on that page nor elsewhere in the brief or in the record does the Government admit, assert, or imply that the mere presence of any amount of aflatoxin in corn "may render it injurious to health." On the contrary, the Government's brief makes clear that the FDA's 20 ppb action level for aflatoxin in corn was its best determination of the *minimum* level at which a violation of § 402(a)(1) might be deemed to occur. One of the considerations on which the action level was

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[7]Pet. App. 4a (emphasis added). The court does not actually cite or quote § 402(a)(1) at this point, but the underlined words in the first sentence of the quoted passage are obviously a reference to and application of the operative language of the first clause of § 402(a)(1), and the underlined words in the second quoted sentence are clearly intended to state that corn containing aflatoxin is adulterated under § 402(a)(1), in the absence of a § 406 tolerance.

[8]Appellee's Brief in the court of appeals ("Appellee's Brief"), at 4.

said to be based was the FDA's conclusion that "[d]irect consumption by humans of corn containing more than 20 ppb of aflatoxin may be injurious to their health." Appellee's Brief at 7. More specifically, the Government stated in its brief that "if corn contains *fewer* than 20 ppb aflatoxin . . . , FDA cannot responsibly recommend regulatory action against the corn because the corn is not adulterated within the meaning of § 402(a)(1)." Appellee's Brief at 34 (emphasis in original). At aflatoxin levels below 20 ppb, *"FDA simply does not have the evidence to prove that the corn may be injurious to health." Id.* (emphasis added).

Thus, far from admitting that the mere presence of aflatoxin in corn would render it adulterated under § 402(a)(1), the Government consistently emphasized that the FDA could *not* establish that 20 ppb aflatoxin or less in corn "may render it injurious to health." There is thus no factual basis in the record for the conclusion that the "presence of aflatoxin in food may render such consumables injurious to health," or the ultimate conclusion that § 402(a)(1) would "define *any* aflatoxin-tainted corn to be adulterated." Pet. App. 4a (emphasis added).

Later on, in Part II of its opinion the court seems to regard § 402(a)(1) as irrelevant. Its attention invited to *Lexington Mill* and *Flemming* and their holding that § 402(a)(1) requires for adulteration a quantity of a contaminant that might be injurious to health, the court distinguished those decisions of this Court on the ground that it is not § 402(a)(1) but § 402(a)(2)(A) "that defines as 'adulterated' food which is unsafe within the meaning of [§ 406]; *Lexington Mill* and *Flemming* thus do not speak to the issue at hand." Pet. App. 15a.

But then, in summing up its conclusion in Part III of the opinion, the court brought § 402(a)(1) back into the picture, and in such a way as to indicate that the court considered § 402(a)(1) to be an absolute standard banning foods containing any amount of a contaminant in the absence of a tolerance. The court there said that it had concluded that "the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulaterated for the purposes of 21 U.S.C. § 342(a)(1) [§ 402(a)(1)] . . . ." Pet. App. 15a.

This vacillation of the court between relying on and discounting § 402(a)(1) as a basis for its invalidation of action levels should not be allowed to obscure the facts that the mere presence of aflatoxin does not automatically render corn adulterated under § 402(a)(1) and that a 20 ppb action level for aflatoxin in corn cannot be regarded as invalid under § 402(a)(1) as a matter of law. Whether §§ 402(a)(2)(A) and 406 provide an independent basis for concluding that all aflatoxin-tainted corn is adulterated in the absence of a § 406 tolerance — as the court suggests in attempting to distinguish *Lexington Mill* — is addressed in the following section.

B. Sections 402(a)(2)(A) and 406 Do Not Prescribe An Adulteration Standard For Unavoidable Added Poisonous Substances For Which No Tolerance Has Been Adopted

The first clause of § 402(a)(1), then, prescribes the general statutory safety standard for foods containing added poisonous or deleterious substances, providing that a food shall be deemed to be adulterated if such a substance is present in sufficient quantity that it might render the food injurious to health. Section 402(a)(2)(A) also applies to added poisonous or deleterious substances, but *only* when such a substance is deemed "unsafe" within the meaning of § 406. This latter section provides that an added poisonous or deleterious substance shall be deemed

"unsafe" for purposes of § 402(a)(2)(A) under only two circumstances.

Under the first clause of § 406, *any* amount of an added poisonous or deleterious substance is unsafe if it is *not* required in the production of food or is *not* unavoidable.[9] For this particular category of added substances, then, §§ 406 and 402(a)(2)(A) establish an absolute, non-quantitative standard which may be invoked by the FDA in place of § 402(a)(1) to establish adulteration of a food without the need to demonstrate in court that the quantity of the added substance might render the food injurious to health.

The second category of added poisonous or deleterious substances deemed "unsafe" under § 406 consists of those which *are* required in production or *are* unavoidable, *and* for which a § 406 tolerance has been adopted, if they are present in an amount above the tolerance. The section goes on to provide that while such a tolerance is in effect, a food containing the substance is not considered adulterated under the general adulteration standard of § 402(a)(1). This latter provision thus avoids a conflict between the case-by-case enforcement approach of § 402 (a)(1) and the substantive rulemaking approach of § 406, so that in appropriate circumstances the FDA may adopt a § 406 tolerance below, at, or above the level that would constitute adulteration under § 402(a)(1), and thereafter establish adulteration under § 402(a)(2)(A) by showing

[9]The terms "required in the production" of food, and "cannot be avoided by good manufacturing practice" are not defined in the Act or regulations. *See* 21 C.F.R. Part 109. Their scope and legislative history are discussed in Merrill, *Regulating Carcinogens in Food*, 77 Mich. L. Rev. 171, 197 n.90 (1978). The scope and applicability of these terms are not in issue in this case, since the FDA found aflatoxin to be unavoidable and that finding was not challenged by the respondents or questioned by the court of appeals.

that food contains the substance in excess of the tolerance.[10]

The language of § 406 — on which the court purports to place such reliance — does *not* prescribe a safety standard for required or unavoidable added poisonous or deleterious substances for which a tolerance has *not* been adopted. Both the wording and general scheme of the statute thus dictate that this particular category of added poisonous or deleterious substances is governed by the quantitative "may render" standard of § 402(a)(1), and that §§ 402(a)(2)(A) and 406 have applicability only to foods containing substances that are explicitly deemed "unsafe" within the meaning of § 406.

The court below of course reached a contrary conclusion, focusing almost exclusively on "[t]he presence of the critical word 'shall' " in § 406, which it says "plainly *suggests* a directive to the Secretary to establish a tolerance, if a food with an unavoidable poisonous or deleterious substance is to be considered unadulterated." Pet. App. 6a (emphasis added). The FDA contended that the decision to proceed by action levels under § 402(a)(1) rather than tolerances under § 406 lies within the Secretary's discretion, since he is directed to promulgate regulations "limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health." In rejecting this contention of the FDA, the court concluded

[10]Tolerances under § 406 limit the quantity of the substance "to such extent as [the Secretary] finds necessary for the protection of public health," taking "into account the extent to which the use of the substance is required or cannot be avoided in the production of each such article, and other ways in which the consumer may be affected by the same or other poisonous or deleterious substances." The FDA thus has considerable discretion in prescribing tolerance levels under § 406, subject to the substantial evidence standard of § 701(f)(3). 21 U.S.C. § 371(f)(3).

"from the structure of the sentence" that the "to such extent" clause does not modify "shall" but rather "explains the standard that the Secretary is to employ in setting the tolerance."[11]

The court of appeals purported to find support for its reading of § 406 in the "overall structure" of the section, and in particular in the second sentence, which in the court's words provides "that, when a regulation establishing a tolerance is in effect, such food will not be considered adulterated." Pet. App. 7a. On this basis, the court concluded:

> Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce.

The court's paraphrases of the second sentence of § 406 in these quoted excerpts omit the concluding phrase of that sentence – "within the meaning of clause (1) of section 402(a)."[12] This omission is apparently not inadver-

[11]Pet. App. 7a. Standing by itself the structure of this sentence could arguably support either the FDA's or the court's interpretation. But it is difficult to see how the court could be so assured that the FDA's long-standing interpretation is impermissible and "flies in the teeth of Congress' clear intent." Pet. App. 6a. The issues of Congressional intent and the court's obligation to give deference to the FDA interpretation are addressed at pp. 17-21 and 21-23, *infra*.

[12]The second sentence reads in full: "While such a regulation is in effect limiting the quantity of such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a)." As previously noted, this provision assures that when a tolerance has been adopted, §§ 402(a)(2)(A) and 406 will govern rather than the case-by-case standard of § 402(a)(1). *See* text and note at p. 10, *supra*.

tent for when the court earlier quoted § 406 at length in its opinion, it elided from the second sentence the phrase "within the meaning of clause (1) of section 342(a) of this title." Pet. App. 4a. This suggests that the court simply does not fully understand the statutory scheme. The ultimate standard for a food is adulteration. The mere existence of a formal tolerance level for a contaminant does not, of course, prevent a food containing any quantity of the contaminant from being adulterated. If the quantity exceeds the tolerance level, the contaminant is "unsafe" under § 406 and therefore the food is adulterated under § 402(a)(2)(A).

The court's misunderstanding of § 406 in this regard may have contributed to the basic logical fallacy in its statutory interpretation. From the major premise, "the existence of a regulation operates to render the food legally unadulterated" (if a tolerance, then food not adulterated) the court concluded that the *absence* of a tolerance implies the food *is* adulterated. The court's reasoning is doubly flawed. Its major premise is wrong because it misstates the statute. And the laws of logic provide that denial of the antecedent in a major premise does not imply denial of the consequent.[13] Thus both logic and the language of the statute clearly support the conclusion that if no tolerance is in effect for an unavoidable added substance, § 406 has no application, and the general safety standard of § 402(a)(1) governs.

The court of appeals interpreted § 406 as if it provided that an added unavoidable poisonous or deleterious sub-

[13]An argument of this form (if A, then not B; not A, therefore B), is said to commit the Fallacy of Denying the Antecedent. Copi, *Introduction to Logic*, 234, 274 (1972).

stance shall be deemed unsafe *unless* a tolerance is in effect. But when Congress has intended to impose such a requirement, it has done so explicitly, not by implication or "suggestion." Sections 408(a), 409(a), and 706(a) provide that a pesticide, or a food additive, or a color additive shall be deemed to be unsafe "unless" a lawfully prescribed tolerance or exemption is in effect.[14] The wording of each of these provisions indicates that they were to some extent modeled on the language of § 406, but in each case the "unless" clause – not present in § 406 – was added. The court of appeals opinion does what Congress deliberately decided not to do – interpret § 406 as if it read exactly like §§ 408(a), 409(a), and 706(a).

Further, the court's interpretation of § 406 has the effects of rendering totally inoperative the Act's basic safety standard in § 402(a)(1). Sections 402(a)(2)(A) and 406 establish an absoltue ban for added poisonous or deleterious subtances that are *not* required or unavoidable, so that the "may render" standard of § 402(a)(1) need have no application to such substances. And §§ 402(a)(2)(A) and 406 explicitly displace § 402(a)(1) when a tolerance has been adopted for an added poisonous or deleterious substance that *is* required or unavoidable. That leaves the first clause of § 402(a)(1) to apply *only* to unavoidable or required added poisonous or deleterious substances for which a tolerance has *not* been prescribed. If the court below is correct, then this latter category is also governed by §§ 402(a)(2)(A) and 406, and the first clause of § 402(a)(1) has been totally inoperative since it and § 402

[14]21 U.S.C. §§ 346a(a), 348(a), 376(a). These pre-market regulatory schemes were enacted by Congress between 1954 and 1960. The three categories of substances are explicitly excepted from § 402(a)(2)(A).

(a)(2)(A) were enacted together in 1938.[15] The court's interpretation clearly offends the "well-settled rule that all parts of a statute, if possible, are to be given effect." *American Textile Manufacturers Institute, Inc. v. Donovan,* 452 U.S. 490, 513 (1981); *Fidelity Federal Savings & Loan Ass'n. v. de la Cuesta,* 458 U.S. 141, 163 (1982).

C. Respondents' Interpretation Of The Act Concedes That The Holding Of The Court Of Appeals Is In Error

In their brief in opposition to the Government's Petition, respondents conceded that § 402(a)(1) continues to apply to added poisonous or deleterious substances "for which the FDA has not yet issued a tolerance." Respondents' Brief 9. This assertion is of course directly contrary to the holding of the court of appeals that the FDA is required to establish tolerances "in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes" of § 402(a)(1). Pet. App. 15a. It is respondents' acknowledgement of the literally impossible practical situation that the decision they urged on the court of appeals would create.

Under the respondents' new theory the first clause of § 402(a)(1) applies to an added poisonous or deleterious substance "until sufficient time has elapsed for the agency to comply with the procedures" of § 701(e). Respondents' Brief 9. Respondents cite *no* statutory language, legislative history, or other authority to support their view of

[15]The legislative history of these provisions indicates that Congress clearly envisioned § 402(a)(1) as having independent substantive effect. *See* p. 18, *infra.*

§ 402(a)(1) as merely a transitional provision, and they do not explain whether, or at what point, § 402(a)(1) ceases to apply if the FDA has not adopted a § 406 tolerance for a known contaminant.[16]

Further, the respondents' new statutory theory is inconsistent with the kind of suit that they filed against the FDA. What they should have done under this theory was initially to petition the FDA to adopt a § 406 tolerance for aflatoxin pursuant to the agency's procedural regulations,[17] and then seek review in court if the FDA denied that petition. Respondents did not follow that course. Instead, they filed a complaint in the district court challenging the validity of the FDA action levels for aflatoxin on legal and procedural grounds. The only issue reached by the court of appeals in reviewing the district court's dismissal of respondents' complaint, and the only issue thus now before this Court, is the court's determination that the aflatoxin action levels are invalid as a matter of law because § 402(a)(1) and/or § 406 automatically render foods containing any amount of aflatoxin adulterated in the absence of a § 406 tolerance.

That unprecedented interpretation of the statute finds no support in the language of the Act; the court of appeals opinion cites no authority that has ever interpreted the Act in this manner; and even respondents now in effect concede that the court of appeals' reading of the statute was in error.

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[16]Congress has frequently enacted transitional provisions to apply for a specified period pending the implementation of a new regulatory program by the FDA. *See, e.g.*, 74 Stat. 404 (1960) (color additives); 72 Stat. 1788 (1958) (food additives); 68 Stat. 517 (1954) (pesticide chemicals).

[17]21 C.F.R. § 10.30.

II. THE 1938 LEGISLATIVE HISTORY OF SECTIONS 402(a) AND 406 MAKES CLEAR A CONGRESSIONAL INTENTION THAT CONTRADICTS THE READING OF THESE PROVISIONS BY THE COURT OF APPEALS

In response to the request of the parties below that the court consider the legislative history of the statutory provisions at issue, the court purported to "find little guidance in the legislative history and certainly not the clear intention necessary to counter the expression of clear language of the statute." Pet. App. 9a. The court's discussion of the legislative history focused exclusively on three documents: a 1935 Senate Report,[18] a 1937 House Committee print,[19] and the 1938 House Report on the final version of the bill.[20]

These three documents standing alone, and considered outside of the context of the five-year legislative history of the Act, may at most support the view that Congress did not make clear its intent with respect to the interpretation and application of the Secretary's authority under § 406. But if the legislative history as a whole is considered, in the light of the contemporary understanding and intent with respect to the statutory provisions, there is no room for reasonable doubt that the FDA's long-standing interpretation of §§ 402(a) and 406 accurately reflects what Congress had in mind.[21]

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[18]S. Rep. No. 646, 74th Cong., 1st Sess. (1935).

[19]House Committee on Interstate and Foreign Commerce, 75th Cong., 1st Sess., Committee Print No. 3 (August 19, 1937), *reprinted* in 81 Cong. Rec. (Appendix) 2341, 2344 (August 21, 1937).

[20]H.R. Rep. No. 2139, 75th Cong., 3d Sess. (1938).

[21]For an excellent contemporary review of the enactment of the 1938 Act, *see* Cavers, *The Food, Drug, and Cosmetic Act of 1938: The Legislative History and Its Substantive Provisions*, 6 Law & Contemp. Problems 2 (1939).

The following summary of some of the principal highlights of the five-year legislative history, together with the chart in Appendix A setting forth the development of the statutory provisions ultimately enacted as §§ 402(a) and 406, clearly demonstrates the Congressional intent in this regard:

1. The 1906 Act included no authority for the promulgation of formal tolerances for added poisonous or deleterious substances. Appendix A, item 1. The FDA did adopt informal tolerances for a number of pesticide sprays in order to advise the public of the level at which it would initiate enforcement action, but it was necessary to prove in each case that the amount in the product was such that it might render the food injurious to health. *United States v. Washington Dehydrated Food Co.*, 89 F.2d 606 (8th Cir. 1937).

2. One of the purposes of the proposed new food and drug law was to authorize the FDA to promulgate regulations prohibiting or establishing formal tolerances for specific added poisonous or deleterious substances, primarily pesticide sprays. Cavers, *supra* n. 21, at 14-15.

3. The language of the proposed statutory provisions, as well as the 1934 Senate Report on the legislation, made it quite clear that these tolerances or prohibitions were authorized and not required in every case, and that the general adulteration standard would "apply to foods containing added poisons for which no tolerance had been set and which for that reason would not be subject to section 3(a)(2)," the legislative forerunner of § 402(a)(2). Appendix A, item 2.

4. Subsequent changes in wording further refined these provisions in the 74th and first session of the 75th Congress, but they retained the basic approach of authorizing

and not requiring the adoption of tolerances.[22] Nowhere in the hearings, reports or debates was it ever suggested that the FDA was required to issue prohibitions or tolerances for all added poisonous substances, or that its failure to issue tolerances would automatically render foods adulterated if they contained any amount of such substances.

5. The wording changes incorporated by the House committee in these provisions in 1938 were not explained in the Report or in the debates, but there was no indication that the change in § 406 from "is authorized to" to "shall" was intended to reorient the previously consistent Congressional intent, and thereby totally displace the operative effect of § 402(a)(1). Indeed, the committee Report stated, as had its predecessors, that "the establishment of tolerances is authorized." Appendix A, item 8. At the same time, the committee added to § 406 the sentence rendering § 402(a)(1) inapplicable when a tolerance had been adopted, in order to avoid the possibility of a conflict between the two sections. If the change from "is authorized to" to "shall" had been intended to have the effect asserted by the court of appeals, rendering any such substance unsafe in the absence of a tolerance, the committee surely would have added a sentence to that effect — as Congress did some years later in §§ 408(a), 409(a), and

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[22]Appendix A, items 3-7. One of these changes, made by the House committee in 1936, revised the second clause of then § 305 [predecessor to § 406] as follows: "but when such substance is so required or cannot be so avoided, the Secretary is authorized to promulgate regulations limiting the quantity therein or thereon *to such extent as he finds necessary for the protection of public health.*" Appendix A, item 5. The "to such extent" clause was thus added at the end of the sentence when the section still "authorized" the promulgation of regulations, and clearly was intended to control *whether* a tolerance should be adopted and the level at which it should be set.

706(a) — rather than leave such a far-reaching result to be implied or suggested.

6. One of the two or three major issues in the debate on the final bill in the House in June of 1938 concerned the procedures by which the FDA would promulgate tolerances under § 406. Cavers, *supra* n. 21 at 20-21. Congressmen from apple-producing states had been successful in writing rigorous rulemaking and judicial review provisions into the House committee bill in order to protect their constituents from unduly restrictive tolerances for pesticide sprays.[23] At no time was it suggested in the Reports or the extensive floor debates[24] that failure of the FDA to promulgate tolerances, or the invalidation of a tolerance by a reviewing court, would render adulterated all foods containing any amount of pesticide residues. Clearly the efforts to protect apple growers from unduly restrictive tolerances were premised on the universal understanding that in the absence of tolerances, the FDA would be required to proceed as it had under the 1906 Act, on a case-by-case basis by demonstrating in court that the

[23]Cavers, *supra* n. 21 at 20-21. The pros and cons of the House procedural language were set forth in the House Committee and Minority Reports. H.R. Rep. No. 2139, 75th Cong., 3d Sess. 9-12 (April 14, 1938); H.R. Rep. No. 2139, Part 2, 75th Cong., 3d Sess. 1-5 (April 21, 1938). If the committee's change from "is authorized to" to "shall" in § 406 was intended to render adulterated foods containing *any* pesticide residues unless a tolerance were adopted, the majority committee members would have referred to this fact in the Report and in the debates, in view of their preoccupation with the effect of § 406 on the use of pesticides by apple growers.

[24]*See, e.g.*, 83 Cong. Rec. 7774 (1938) (including statements by the committee Chairman that the Secretary "shall have *authority* after proper hearing to prescribe the extent of spray residue that shall be permissible," and that he would have "the *right* after proper hearings to adopt regulations prescribing limits") (emphasis added); 83 Cong. Rec. 7782-85, 7891-98 (1938); 83 Cong. Rec. 9096-9100 (1938) (House debate on the Conference Report).

quantity of the residue might render the apples injurious to health under § 402(a)(1).[25]

The interpretation of § 402(a)(1), § 402(a)(2)(A), and § 406 espoused by the court below is thus totally at odds with the statute as it was proposed, explicitly explained in the initial Senate Report, debated, and enacted by Congress in 1938, and as it has been consistently interpreted and applied by the FDA since that time.

III. THE COURT OF APPEALS DISREGARDED ITS OBLIGATION TO GIVE "CONSIDERABLE DEFERENCE" TO THE AGENCY'S LONG-STANDING INTERPRETATION OF THE ACT

Nowhere in the opinion below does the court acknowledge the teaching of this Court that "an agency's construction of a statute it is charged with enforcing is entitled to deference if it is reasonable and not in conflict with the expressed intent of Congress." *United States v. Riverside Bayview Homes, Inc.*, 54 U.S.L.W. 4027, 4030 (Dec. 4, 1985). As stated in *Chemical Manufacturers Ass'n v. Natural Resources Defense Council, Inc.*, 105 S. Ct. 1102, 1108 (1985):

> [The] view of the agency charged with administering the statute is entitled to considerable deference; and to sustain it, we need not find that

[25]That is of course exactly what happened, as the FDA decided not to undertake the procedures necessary for promulgation of § 406 tolerances. Sixteen years later Congress enacted § 408, 21 U.S.C. § 346a, in order to establish a pre-market approval system for pesticides used in or on agricultural commodities. Section 406 was retained in the Act to continue to prohibit avoidable or unrequired added poisonous or deleterious substances, and to authorize tolerances for unavoidable or required added poisonous or deleterious substances other than pesticides on raw agricultural commodities.

> it is the only permissible construction that [the agency] might have adopted but only that [the agency's] understanding of this very "complex statute" is a sufficiently rational one to preclude a court from substituting its judgment for that of [the agency].

The court of appeals alluded to this doctrine in citing *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1566 (D.C. Cir. 1984) (*en banc*), and *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 104 S. Ct. 2778, 2781 (1984), for the proposition that if the intent of Congress is clear, the court must give effect to that intent and reject a contrary administrative construction. Pet. App. 5a, 6a. What the court did not say is that the administrative construction was *upheld* in both cases. In *Chevron* this Court described the administrative interpretation as "a reasonable policy choice for the agency to make," and reversed a decision by the Court of Appeals for the District of Columbia Circuit which "misconceived the nature of its role in reviewing the regulations at issue." 104 S. Ct. at 2783.

The court of appeals purported to rely on the "clear language of the statute" in rejecting the FDA's long-standing interpretation.[26] As demonstrated in the first section of this brief, however, the court's holding depends on its unsupported and selective interpretation of a single provision in § 406, involves reading into that section a safety standard for a category of substances that are simply not referred to in the statutory language, and requires an interpretation of § 402(a)(1) that has been squarely rejected by this Court. Surely the court of appeals "misconceived the nature of its role in reviewing the regulations at issue."

[26]Pet. App. 9a. After enactment of the 1938 Act the agency continued to rely on informal action levels under § 402(a)(1) rather than invoking the cumbersome procedures required for § 406 tolerances. *See, e.g.*, United States v. 449 Cases, etc., 212 F.2d 567, 575 (2d Cir. 1954) (including Judge Frank's persuasive dissent); United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980). In 1957 the FDA stated that "the act clearly contemplates that the Government may proceed against a contaminated food under section 402(a)(1) of the act when no tolerance is effective." 42 Fed. Reg. 52818 (Sept. 30, 1977).

IV. THE COURT OF APPEALS DECISION IMPOSES AN INTOLERABLE BURDEN ON THOSE RESPONSIBLE FOR MAINTAINING AN ADEQUATE FOOD SUPPLY

In holding that the FDA must issue § 406 tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated, the court of appeals has arrived at an unprecedented interpretation of the Act that renders a very substantial portion of the food supply adulterated and thus unlawful for shipment in interstate commerce. The court below[27] and other federal courts[28] have for the most part accepted the FDA's broad reading of the word "added," so that it encompasses environmental, agricultural, industrial, or other contamination that is attributable at least in minute part to the acts of man, whether by deliberate use or accidental occur-

[27]Pet. App. 3a.

[28]United States v. Anderson Seafoods, Inc., 622 F.2d 157, 161 (5th Cir. 1980) (traces of mercury in fish from both natural and human sources regarded as "added"); Continental Seafoods, Inc. v. Schweiker, 674 F.2d 38, 43 (D.C. Cir. 1982) (salmonella in fish held to be "added" on the gorund that salmonella "can result" from insanitary processing procedures).

rence. *See* p. 6, *supra*. Further, such contamination is recognized as being ubiquitous and unavoidable for commodities raised in or procured from the natural environment. As stated by the FDA:

> The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities.[29]
>
> * * *
>
> If a nondetectable-residue requirement were automatically applied to environmental contaminants already present in the food supply, enforcement activities could significantly disrupt the food supply.[30]

If § 406 tolerances are deemed to be the only means by which the FDA may legitimize the shipment of foods containing environmental and agricultural contaminants, as held by the court below, then there is no realistic prospect that the FDA and the food industry can reconcile the practical need to continue production and distribution of the food supply with the pronouncement of this Court that "the Act imposes [on food company officials] not only a positive duty to seek out and remedy violations when they occur but also, and primarily, *a duty to implement measures that will insure that violations will not occur.*" *United States v. Park*, 421 U.S. 658, 672 (1975) (emphasis added).

The Government's Petition documents the literal impossibility of the FDA's initiating and completing within the foreseeable future proceedings for the establishment of

[29] 42 Fed. Reg. 52814 (Sept. 30, 1977).

[30] 42 Fed. Reg. 17490 (April 1, 1977).

formal tolerances for all detectable environmental contaminants.[31] Adoption of formal tolerances only for the contaminants now subject to published action levels would take a number of years to complete. In the meantime, farmers and food company officials would be faced with the necessity of choosing between seriously disrupting the nation's food supply or intentionally exposing themselves to criminal prosecution.

CONCLUSION

For the foregoing reasons, the decision of the court below should be reversed.

Respectfully submitted,

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[31] Pet. 15-16. The court below was apparently unaware of the protracted rulemaking procedures that must be observed in the promulgation of § 406 tolerances, for it refers to the plaintiffs' suit as one to require the FDA to adopt "by way of notice-and-comment rulemaking" formal tolerances as opposed to informal action levels. Pet. App. 2a. Tolerances under § 406 may of course be adopted only pursuant to the complex and protracted procedures prescribed in § 701(e).

APPENDIX A

Summary of the Legislative History Of Sections 402(a)(1) and (2) and 406
Of The Federal Food, Drug, and Cosmetic Act of 1938,
21 U.S.C. §§ 342(a)(1) and (2), 346, 52 Stat. 1046, 1049
(*Underlining* and ~~*interlining*~~ indicate changes from previous version)

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
1. Federal Food and Drug Act of 1906 (34 Stat. 768)	"SEC. 7. [F]or the purposes of this Act an article shall be deemed to be adulterated: . . . In the case of food: . . . Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health."	No comparable provision.
	COMMENT: The 1906 Act applied only to "added" poisonous or deleterious ingredients, not to natural constituents of food. It contained no provision for the promulgation of tolerances for poisonous or deleterious substances.	
2. S. 2800 (as introduced, 73d Cong., 2d Sess., Feb. 2, 1934 and as reported to the Senate, S. Rep. No. 493, 73d Cong., 2d Sess. 3-4, March 15, 1934)	"SEC. 3. A food shall be deemed to be adulterated – "(a)(1) If it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance prohibited, or in excess of the limits of tolerance prescribed, by regulations as provided by sections 10 and 22; . . . ."	"SEC. 10 (a) If an added poisonous or added deleterious substance in or on food . . . is or may be injurious to health, the Secretary is hereby authorized to promulgate regulations . . . prohibiting such added substance in or on any food . . . or establishing tolerances limiting the amount therein or thereon, for the protection of public health, taking into account the extent to which the use of such substance is required in the production of such food . . . ."
	COMMENT: In explaining these provisions, the Senate Report stated that: "Paragraph 3(a)(1) . . . applies to foods which by reason of the poisonous or deleterious constituent may be dangerous, irrespective of whether that constituent is added by man or put there by nature . . . . *It would also apply to foods containing added poisons for which no tolerance had been set and which for that reason would not be subject to section 3(a)(2).*" (Emphasis added).	

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
3. S. 5 (as introduced, 74th Cong., 1st Sess., Jan. 3, 1935)	§ 301(a)(1) and (2) – *no change* from S. 2800, § 3(a)(1) and (2), in 73d Congress.	§ 304(a) – *no change* from S. 2800, § 10(a), in 73d Congress.
	COMMENT: The 74th Congress started out with the bill as it had been reported by the Senate committee in the 73d Congress.	
4. S. 5 (as reported to the Senate, S. Rep. No. 646, 74th Cong., 1st Sess., May 13, 1935; and passed by the Senate, 79 Cong. Rec. 8356, May 28, 1935)	"SEC. 301 A food shall be deemed to be adulterated – (a)(1) if it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance *which may render it injurious to health, or which is* prohibited *by § 304*, or in excess of the limits of tolerance prescribed by regulations as provided by §§ 304, 701, and 703."	"SEC. 304. (a) To safeguard the public health, no poisonous or deleterious substance shall be added to any food except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice; but when such substance is so required or cannot be so avoided, the Secretary is authorized, for the protection of public health, to promulgate regulations, as provided by sections 701 and 703, limiting the quantity therein or thereon . . . ."
	COMMENT: The 1935 Senate-passed version of S. 5 retained the basic approach of the earlier bills, but made several key modifications. The "dangerous to health" standard was retained for naturally occurring ingredients in § 301(a)(1). Section 301(a)(2) was revised to incorporate the "may render injurious to health" standard of the 1906 Act for "added" substances, unless they were prohibited by § 304. Section 304 was rewritten so that any added poisonous substance would be prohibited unless it was required or unavoidable; as in the earlier bills, the Secretary was "authorized" to promulgate tolerances, but now only for required or unavoidable substances.	

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
5. S. 5 (as reported to the House, H. Rep. No. 2755, 74th Cong., 2d Sess., May 22, 1936)	"SEC. 301. A food shall be deemed to be adulterated – (a)(1) if it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance which may render it injurious to health, or which is *unsafe within the meaning of* section *305*, or in excess of the limits of tolerance prescribed by regulations as provided by section *305*."	"SEC. 304 *305*. (a) ~~*To safeguard the public health, no*~~ *Any* poisonous or deleterious substance ~~*shall be*~~ added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice *shall be deemed to be unsafe for purposes of the application of section 301(a);* but when such substance is so required or cannot be so avoided, the Secretary is authorized, ~~*for the protection of public health,*~~ to promulgate regulations ~~*as provided by sections 701 and 703,*~~ limiting the quantity therein or thereon *to such extent as he finds necessary for the protection of public health* . . . ."
	COMMENT: The 1936 House Report did not elaborate upon the indicated revisions, except to note that §§ 301(a)(2) and 305 were revised to speak in terms of "unsafe" rather than a prohibition, apparently out of concern as to the reach of Congress' power over commerce. The limitation on the Secretary's authority to promulgate tolerances was added – "to such extent as he finds necessary for protection of public health." At this point it was clear that this limitation controlled both *whether* a tolerance should be adopted *and* the level at which it would be set.	
6. S. 5 (as introduced, 75th Cong., 1st Sess., Jan. 6, 1937)	§ 11(a)(1) and (2) – *no change* from § 301(a)(1) and (2) of S. 5 as reported to the House in the 74th Congress.	§ 15(a) – *no change* from § 305 of previous House bill, except that "contaminating" was added to precede "poisonous."

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
7. S. 5 (as reported to the Senate, S. Rep. No. 152, 75th Cong., 1st Sess., March 8, 1937; and passed by the Senate, 81 Cong. Rec. 2009, 2010, 2019, March 9, 1937)	"§ 11. A food shall be deemed to be adulterated – (a)(1) if it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance which may render it injurious to health, or which is unsafe within the meaning of section 305, ~~*or in excess of the limits of tolerance prescribed by regulations as provided by section 305*~~."	§ 15(a) – no change, except for adding at the end of the first sentence the words "and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of section 11(a)."
	COMMENT: The 1937 Senate-passed bill left essentially unchanged the bill as it had been reported out by the House committee in the previous Congress. It remained clear that the first clause of § 11(a)(2) applied to required or unavoidable substances for which no tolerance had been set.	
8. S. 5 (as reported to the House, H. Rep. No. 2139, 75th Cong., 3d Sess., April 14, 1938, passed by the House, 83 Cong. Rec. 7903, June 1, 1938; and approved by the President, Pub. L. No. 717, 75th Cong., June 25, 1938)	"SEC. 402. A food shall be deemed to be adulterated – "(a)(1) If it bears or contains any poisonous or deleterious substance which may render it ~~*dangerous*~~ *injurious* to health; *but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;* or (2) if it bears or contains any added	"SEC. 406. (a) Any ~~*contaminating*~~ poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary *is* ~~*authorized to*~~ *shall* promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
	poisonous or added deleterious substance which ~~may render it injurious to health, or which~~ is unsafe within the meaning of section 406; . . . ."	limits for fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402(a). *While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a) . . . ."*

COMMENT: The House committee made a number of wording revisions throughout the bill. It revised § 402(a)(1) by changing "dangerous" to "injurious," thus moving from § 402(a)(2) the "may render injurious to health" standard applicable to "added" substances. The committee added to § 402(a)(1) a new "ordinarily" injurious standard for not added substances. Section 402(a)(2) was thus left to deal solely with "unsafe" substances under § 406. In this latter provision "shall" was substituted for "is authorized to," and a new second sentence was added to make clear that § 402(a)(2) controlled rather than § 402(a)(1) *when a tolerance had been prescribed.* (In a number of other places throughout the bill the committee substituted "shall" for "is authorized to." In §§ 401 and 404, for example, it remained clear that the Secretary was to adopt regulations *if* he made the prescribed finding or judgment.)

None of these changes were elaborated upon in the Report; but like all previous reports it stated that under § 406 "the establishment of tolerances is authorized." H. Rep. No. 2139, 75th Cong., 3d Sess. 6 (April 14, 1938).

No. 85-664

(8)

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,

Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

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BRIEF FOR GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE IN SUPPORT OF THE PETITIONER

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QUESTION PRESENTED

Does the Federal Food, Drug, and Cosmetic Act of 1938 authorize the Food and Drug Administration to determine, through exercise of its administrative discretion, whether to regulate added poisonous or deleterious substances in the food supply by (1) establishing informal "action levels" that constitute criteria for determining when the FDA will initiate court enforcement proceedings under Section 402(a)(1) of the Act, without (2) establishing formal "tolerances" through rulemaking on a record under Section 406 of the Act that constitute substantive requirements under the Act?

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

No. 85-664

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

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BRIEF FOR GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE IN SUPPORT OF THE PETITIONER

INTEREST OF AMICUS CURIAE

The Grocery Manufacturers of America, Inc. (GMA), is a trade association representing companies that manufacture food products for nationwide distribution. Its members include the principal grocery manufacturers in this country. Members of GMA ship products in interstate commerce for sale throughout the country and thus are subject to all of the requirements established under the Federal Food, Drug, and Cosmetic Act of 1938 (the FD&C

Act)[1] relating to food safety. GMA and its members therefore have a major interest in assuring that regulatory requirements relating to food safety conform to the provisions of the FD&C Act and impose no more burdensome procedural or substantive requirements than are reasonably necessary to maintain compliance with the Act. GMA and its members strongly support the current Food and Drug Administration (FDA) approach to regulating added poisonous or deleterious substances in the food supply under the FD&C Act, but oppose changes that would be required by the decision of the United States Court of Appeals for the District of Columbia Circuit[2] in this case.[3]

SUMMARY OF ARGUMENT

Under the Food and Drugs Act of 1906, FDA was given enforcement discretion to take regulatory action against any added poisonous or deleterious food ingredient which may render the food injurious to health. In construing this general food safety standard in the *Lexington Mill* case in 1914, this Court determined that it was intended to prohibit any substance that represented a reasonable possibility of harm to human health under actual conditions of use.

When Congress enacted the Federal Food, Drug, and Cosmetic Act of 1938 to replace the 1906 Act, it purposely retained the same wording in Section 402(a)(1) in order to retain the interpretation adopted in *Lexington Mill*. At the same time, Congress realized that not all added poisonous or deleterious substances can or should be prohibited. Accordingly, Section 406 was included in the 1938 Act specifically to authorize FDA to set tolerances for added poisonous or deleterious substances that would otherwise

[1] 52 Stat. 1040 (1938), 21 U.S.C. § 301 *et seq.*

[2] Community Nutrition Institute v. Young, 757 F.2d 354 (D.C. Cir. 1985).

[3] All parties have consented to the filing of this brief by letters that have been filed with the clerk of the court in accordance with Rule 36.

be banned under Section 402(a)(1), where those substances are either "required in the production" of food or "cannot be avoided by good manufacturing practice."

In the legislative history, Congress used three types of examples to illustrate the categories of substances to which Section 406 was intended to apply. First, Section 406 was intended to apply to pesticide residues in food, where the pesticide is necessary to produce the food. Second, Section 406 was intended to apply to a functional food additive, such as a preservative added to prevent rancidity, where it is necessary for the production of the food. Third, Section 406 was intended to apply where a raw material contained a contaminant that could not entirely be eliminated by purification processes, and thus cannot be avoided in good manufacturing practice. When Congress subsequently enacted the Miller Pesticide Amendment in 1954 and the Food Additives Amendment of 1958, more specifically to govern pesticide residues and food additives, Section 406 was nonetheless retained to permit FDA to continue to handle pesticide residues, food additives, and contaminants, under Section 406 as well.

In order to maximize public health protection, FDA has taken an extremely broad interpretation of the scope of the statutory term, "added substance." Under current FDA interpretation, virtually all food substances are regarded as added. With the extraordinary advances since 1938 in science generally, and in analytical chemistry and toxicology in particular, it is now apparent that the food supply contains literally hundreds of added substances that would be considered poisonous or deleterious under extreme conditions but that do not represent a reasonable possibility of harm to human health under actual conditions of human use. FDA now recognizes, for example, that virtually all food contains inherent carcinogenic ingredients or carcinogenic contaminants. As more and more natural food substances are tested, more are found to be carcinogenic or otherwise toxic under some conditions of stringent laboratory testing and experimentation. It is thus apparent that, because of new scientific knowledge, FDA

can identify added poisonous or deleterious substances in every food product marketed in the country today.

To handle this problem, FDA has adopted a very responsible and reasonable regulatory approach. For those poisonous or deleterious substances that do not represent a significant risk, FDA has simply ignored their presence and has not established either an informal action level or a formal tolerance. For those that the Agency has found at levels that could potentially raise public health concern, action levels have been established, and specific regulatory action has been taken, to make certain that they represent no reasonable possibility of harm to human health. In one instance, where there was persistent controversy and litigation, the Agency established a formal tolerance on the basis of a rulemaking on a record.

This system has worked well to protect the American public health. It reflects the congressional intent to retain FDA's discretion to bring enforcement action under Section 402(a)(1), based on the *Lexington Mill* standard.

The court of appeals in the instant case held that a formal tolerance must be promulgated for every added poisonous or deleterious substance in the food supply. It is clear that the court of appeals did not understand the implications of its holding. Such a task would overwhelm FDA. It is contrary to the legislative history, to the statutory purpose of Section 406, and to common sense and good government. If FDA were to devote all of its resources to such a task, it is unlikely that it could be accomplished in the foreseeable future. Thus, under the decision of the court of appeals, virtually the entire United States food supply would remain unlawful for decades to come. Such an implausible result could hardly have been intended by Congress and should be rejected by this Court.

ARGUMENT

I. Congress Intended FDA to Have Discretionary Authority to Regulate Added Poisonous or Deleterious Substances Either by Court Enforcement Proceedings Under Section 402(a)(1) or by Rulemaking Under Section 406.

A. Under the 1906 Act, FDA Had Authority to Regulate Added Poisonous or Deleterious Ingredients by Court Enforcement Proceedings.

In 1906, when the first national food safety legislation was enacted,[4] Congress declared that a food was adulterated, and thus illegal, if it contained:

> ". . . any added poisonous or other added deleterious ingredient which may render such article injurious to health . . ."[5]

In construing this statutory prohibition in the *Lexington Mill* case in 1914,[6] the Supreme Court rejected both the argument made by industry on the one extreme that food could be condemned only if it was shown actually to injure health, and the argument made by the government on the other extreme that food must be condemned if it contained even a harmless amount of a substance that would be poisonous or deleterious at a higher level:

> "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of establishing, in order to secure a verdict of condemnation under this statute, that the

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[4]Food and Drugs Act of 1906, 34 Stat. 768 (1906).

[5]Section 7, 34 Stat. at 770.

[6]United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914).

added poisonous or deleterious substances must be such as may render such article injurious to health. The word 'may' is here used in its ordinary and usual signification, there being nothing to show the intention of Congress to affix to it any other meaning. It is, says Webster, 'an auxiliary verb, qualifying the meaning of another verb, by expressing ability . . . contingency or liability, or possibility or probability.' In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the old and the young, the well and the sick; and it is intended that if any flour, because of any added poisonous or other deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act."[7]

Thus, this Court took the very reasonable intermediate position that an added poisonous or deleterious substance violated the law if it represented a reasonable possibility of harm to human health under its actual conditions of use.

The scope of the statutory reference to an "added" ingredient under the 1906 Act was also the subject of review by this Court, in the *Coca Cola* case in 1916.[8] The

[7] *Id.* at 411. This Court has, more recently, adopted virtually an identical interpretation in requiring the finding of a significant human risk before regulation may be imposed under the Occupational Safety and Health Act. Industrial Union Dept, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980).

[8] United States v. Coca Cola Co., 241 U.S. 265 (1916).

Court held that a food substance must be regarded as "added" if it was "artificially introduced," whether the addition was "made to a natural food product or to a compound."[9] Indeed, the Court commented that Congress may have supposed "that, ordinarily, familiar food bases would be used for this purpose."[10] This interpretation allowed FDA to pursue a broad and expansive interpretation of the term "added," that the agency has continued to this day.

B. Section 402(a)(1) of the 1938 Act Was Intended to Continue the Lexington Mill Decision.

When Congress enacted the 1938 Act to replace the 1906 Act, it retained, in Section 402(a)(1), the prohibition against any "added substance" in food that is a "poisonous or deleterious substance which may render it injurious to health."[11] The legislative history makes it clear that, although this provision was slightly reworded to fit the context of the new statute, Congress intended to retain the substance and this Court's interpretation of the 1906 Act provision. The Chief of the FDA, W.G. Campbell, testified before Congress in 1934 that the language of the provision in the pending legislation that became the 1938 Act:

> ". . . is the language of the present law. That language has been considered in litigation which was carried to the Supreme Court, and has been exhaustively discussed by that Court.
>
> Now, one of the concerns that we have is, first, the most extensive and most effective protections to the public that can be made. Unquestionably the use of the subjunctive provides that. And, second, to preserve the use of language which

[9] *Id.* at 284.

[10] *Id.*

[11] Section 402(a)(1) of the FD&C Act, 21 U.S.C. § 342(a)(1).

> has already been considered by the Supreme Court."[12]

The committee reports in the Senate, which exercised the lead role in this legislation, reflected this intent of the draftsmen.[13] In fact, this Court has since recognized that its 1914 decision remains the controlling construction of the 1938 Act as well.

> "The language involved in *Lexington Mill* survived generally in the Act's broadest and most general test of food adulteration, § 402(a)(1)."[14]

Thus, Congress intended that the authority of FDA to enforce the statutory prohibition against added poisonous or deleterious substances would remain the same under the 1938 Act as under the 1906 Act.

C. Section 406 of the 1938 Act Was Intended to Authorize FDA to Permit the Continued Use of Added Substances That Would Otherwise Violate Section 402(a)(1).

Between 1906 and 1938, Congress realized that not all added poisonous or deleterious substances that may render food injurious to health can or should be prohibited. Some are vitally needed to produce an adequate supply of food at reasonable cost, and others are unavoidable contaminants. Accordingly, the 1938 Act included, for the first time, a provision, Section 406,[15] authorizing FDA to set tolerances for added poisonous or deleterious substances that would otherwise be banned under Section 402(a)(1) where those substances either are "required in the production" of food or "cannot be avoided by good manu-

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[12]"Foods, Drugs, and Cosmetics," Hearings before the Committee on Commerce, United States Senate, 73d Cong., 2d Sess. 530 (1934).

[13]S. Rep. No. 493, 73d Cong., 2d Sess. 3 (1934); S. Rep. No. 361, 74th Cong., 1st Sess. 6 (1935).

[14]Flemming v. Florida Citrus Exchange, 358 U.S. 153, 161 (1958). *See, e.g.*, United States v. 2,116 Boxes of Boned Beef, Food Drug Cosm. L. Rep. (CCH) ¶ 38,114 (D. Kan. 1981).

[15]21 U.S.C. § 346.

facturing practice."[16] Under either of these circumstances, FDA was given the authority to set formal tolerances, after rulemaking on a record, to establish whatever limitations are necessary for the protection of the public health. This authority was intended to be in addition to, and in no way to detract from, the pre-existing prohibition against added poisonous or deleterious substances that was retained in Section 402(a)(1).

In enacting Section 406, Congress did not define the critical terms "required in the production" or "cannot be avoided." The legislative history does, however, give a number of important examples of the broad and comprehensive application intended for Section 406. From its inception, it is apparent from these examples that Congress intended Section 406 to be potentially available for any added poisonous or deleterious substance, whether it was directly and intentionally added or indirectly and unintentionally added.

The initial legislation considered by Congress only contained the "required in the production" portion of the criteria that were ultimately included in Section 406. The 1934 Senate report explained this portion of Section 406:

> "Section 10(a) authorizes the Secretary to promulgate regulations for any added poison in food and cosmetics, or to establish tolerances limiting the amount. In promulgating such regulations this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances

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[16]For such a substance, Section 402(a)(2)(A), 21 U.S.C § 342(a)(2)(A), provides that the failure to comply with a promulgated tolerance renders the food adulterated and thus unlawful.

for any food where poison is unavoidable or is required by the necessities of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount of poison in a particular food to every [sic] small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add dangerously toxic substances to foods, as, for example, the addition of maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions in manufacture and packaging and by use of refrigeration for the finished product.

In approaching the problem of control from this angle the amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of the various foods consumers will not receive an aggregate quantity of poisons sufficient to jeopardize health."[17]

It is clear from the two examples used in this passage that the Senate intended the "required in the production" language to include direct and intentional addition of a poisonous or deleterious substance to food. The pesticides to which the report referred were sprayed directly on the food. The maleic acid to which the report referred was added directly and intentionally to preserve the food.[18]

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[17]S. Rep. No. 493, 73d Cong., 2d Sess. 4 (1934).

[18]There would have been no purpose in referring to the maleic acid example if Congress had not intended Section 406 potentially to be available for direct and intentional additives. The maleic acid example was used to show that, where a reasonably practicable alternative was available, the additive could not meet the "required" standard established by the provision. Where a method of food preservation is determined to be necessary, such as the use of lead in food canning, FDA has concluded that the "required" standard could be met. 44 Fed. Reg. 51233, 51240 (August 31, 1979).

Subsequently, the "cannot be avoided" portion was added to this provision. The new language was explained in the 1935 Senate report:

> "Section 304(a) prohibits the addition of poisonous or deleterious substances to food except where such addition is required in production, as in the case of poisonous sprays for fruits and vegetables to protect them against insects or fungus diseases, or where such addition cannot be avoided in good manufacturing practice, as where purification processes cannot entirely eliminate a contaminant of raw materials, or where some contaminant is unavoidably introduced in factory operations. This section then authorizes the establishment of tolerances for the protection of public health in those instances where the addition of the poison is required or cannot be avoided. In determining tolerances for different articles of food there must be taken into account the extent to which the poison is required or cannot be avoided and likewise the other ways in which the consumer may be affected by the same or other poisonous substances. The prohibition of added poisons by this section will control those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add toxic substances to food, as, for example, maleic acid to fats or oils to prevent rancidity when the preservation can be accomplished by observance of sanitary conditions in manufacturing and packaging."[19]

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[19]S. Rep. No. 361, 74th Cong., 1st Sess. 6 (1935). The substitute report filed later in the year shortened the description but did not change its substance. S. Rep. No. 646, 74th Cong., 1st Sess. 3 (1935). Neither the minority views expressed with respect to the earlier report nor any aspect of the legislative history between the two reports reflected any disagreement with this portion of the legislation or the earlier report.

The example given by the Senate, in this report, of a substance that "cannot be avoided" was a food contaminant that could not be eliminated by processing. The report also continued to use a directly applied pesticide as an example of an added poisonous or deleterious substance that is "required in the production" of food. The final Senate report, filed in 1937, contained only a brief reference to Section 406.[20]

The House report in 1938 contained basically the same description as had the earlier Senate reports.[21] Once again the direct and intentional addition of pesticides to raw agricultural commodities was given as an example of an added poisonous or deleterious substance that is "required in the production" of food. It was this version of the legislation that was passed by Congress and signed into law.

In 1954, Congress enacted the Miller Pesticide Amendment, adding Section 408 to the FD&C Act to provide additional authority to regulate the direct and intentional addition of pesticides to raw agricultural commodities.[22] Pesticide residues were, of course, one of the two examples given by Congress of the potential use of the "required in the production" portion of Section 406. Nonetheless, Congress did not conclude during the consideration of the 1954 Amendment that the "required in the production" portion of Section 406 was now obsolete or should be limited or otherwise modified. If that portion of Section 406 had indeed been intended by Congress no longer to be available for use in handling the direct and intentional addition of pesticides to food, Congress would have repealed or revised that portion of Section 406. Instead, Section 406 was left intact.

Four years later, Congress enacted the Food Additives Amendment of 1958 to provide additional authority to reg-

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[20]S. Rep. No. 91, 75th Cong., 1st Sess. 5 (1937).

[21]H.R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (1938).

[22]68 Stat. 511 (1954), 21 U.S.C. § 346a.

ulate those substances that are directly and intentionally added to the food supply either directly or indirectly.[23] Once again, Congress did not decide that, upon enactment of the 1958 Amendment, the "required in the production" portion of Section 406 would become obsolete and inoperative. No one recommended repeal or revision of that portion of Section 406, and in fact it was not changed in any way. And no further relevant changes have been made in the FD&C Act since then. Thus, Section 406 has not been amended since it was enacted in 1938.

II. FDA Has Consistently Interpreted and Applied Section 402(a)(1) and Section 406 as Separate Enforcement Provisions.

A. Under Current FDA Interpretation Of The FD&C Act, Virtually All Food Substances Are Regarded As Added Substances.

Under the FD&C Act, food substances are divided into two basic categories: (1) added and (2) non-added. Non-added substances may lawfully be used as food if they are not "ordinarily injurious to health" pursuant to Section 402(a)(1).[24] Added substances are unlawful under Section 402(a)(1) if they "may render [the food] injurious to health." Under the Food Additives Amendment of 1958, added substances that meet the definition of a "food additive" in Section 201(s) of the FD&C Act may be used in food only after FDA has approved them as "safe" in accordance with the provisions of Section 409.[25]

Because the statute imposes a lighter burden on FDA for regulating added substances, FDA has pursued an expansive interpretation of the term "added" and has viewed the "non-added" category as extremely limited and narrow in scope. FDA has stated that a "naturally occurring"

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[23]72 Stat. 1784 (1958), 21 U.S.C. § 348.

[24]United States v. 1232 Cases American Beauty Brand Oysters, 43 F. Supp. 749 (W.D. Mo. 1942).

[25]21 U.S.C. § 321(s) and § 348.

substance is not an added substance,[26] but has narrowly defined a "naturally occurring" substance as a:

> ". . . substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination."[27]

In explaining these definitions, FDA emphasized that any substance that is "not inherently a component of the food" would be regarded as added, and rejected contentions that added substances are only those that occur in food as a result of some human action.[28]

FDA has pursued this interpretation vigorously in the courts. FDA has successfully argued that salmonella is an added substance in eggs[29] and shrimp,[30] aflatoxin is an added substance in corn,[31] DDT is an added substance in fish,[32] and lead migrating from pottery plates is an added substance in food.[33]

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[26]21 C.F.R. § 109.3(d).

[27]21 C.F.R. § 109.3(c).

[28]39 Fed. Reg. 42743, 42744 (December 6, 1974); 42 Fed. Reg. 52814 (September 30, 1977).

[29]United States v. 1200 Cans, Pasteurized Whole Eggs, 339 F. Supp. 131 (N.D. Ga. 1972).

[30]Seabrook International Foods, Inc. v. Harris, 501 F. Supp. 1086 (D.D.C. 1980).

[31]United States v. 1,680,000 Pounds of White Corn, Civil No. T-4173 (D. Kan., December 18, 1970), *in* V. Kleinfeld et al., Federal Food, Drug, and Cosmetic Act Judicial Record 1969-1974,at 214 (1976); United States v. Boston Farm Center, Inc., 590 F.2d 149 (5th Cir. 1979).

[32]United States v. Ewig Bros. Co., Inc., 502 F.2d 715 (7th Cir. 1974).

[33]United States v. Articles of Food . . . Pottery, 370 F. Supp. 371 (E.D. Mich. 1974). The courts have split on the question whether mercury is an added substance in fish. *Compare* United States v. An Article of Food Consisting of Cartons of Swordfish, 395 F. Supp. 1184 (S.D.N.Y. 1975) *with* United States v. Anderson Seafoods, Inc., 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980). *See also* Note, Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish, 85 Harv. L. Rev. 1025 (1972).

The broad sweep of FDA's interpretation of the scope of the term "added" is apparent from the agency's lists of food additives, all of which are necessarily added substances. FDA has unequivocally stated that "Neither that language [in 21 U.S.C. § 321(s)] nor the legislative history of the Food Additives Amendment reveals an intent to exclude natural food constituents from regulation as food additives."[34] Just before enactment of the Food Additives Amendment of 1958, FDA submitted a list of illustrative "chemical food additives" to the House of Representatives that included brandy, butter, coffee, corn oil, cream, dried skim milk, lard, lemon juice, mace, margarine, molasses, mustard, olive oil, pepper, salt, sugar, vinegar, and wine.[35]

FDA has thus far delineated no limit to the concept of an "added" substance, other than excluding the inherent natural constituents of a raw agricultural commodity that is marketed and consumed without further processing or

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[34]41 Fed. Reg. 19207, 19208 (May 11, 1976).

[35]"Food Additives," Hearings before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 85th Cong., 2d Sess. 461-462 (1958). FDA Commissioner Edwards testified in 1972 that the term "food additive":

> ". . . is not limited to the artificial or synthetic chemicals that the public most often associates with it. It includes all raw agricultural commodities as well as fabricated food. This means that, for example, the components of beef stew—the carrots and meat, as well as any emulsifiers or stabilizers—must either be classified as GRAS or must be subject to a food additive regulation promulgated by the Commissioner.
>
> The components of butter and ice cream, both of which are fabricated foods, must all be classified as GRAS or be the subject of a promulgated regulation.
>
> In essence, under modern methods of processing and packaging, virtually the entire food supply must be classified either as GRAS or as regulated food additives, or they may not lawfully be permitted to be used as part of the daily diet."

"Nutrition and Human Needs," Hearings before the Select Committee on Nutrition and Human Needs, United States Senate, 92d Cong., 2d Sess., Pt 4B, at 1199, 1201 (1973).

preparation. As soon as any processing or preparation is undertaken, consistent with judicial precedent beginning with the *Coca Cola* decision and extending to the present, FDA has taken the position that the raw agricultural commodity and every other substance used in making the processed food are all added substances that must individually withstand scrutiny under the provisions of Section 402(a)(1).

B. The Food Supply Contains Hundreds of Added Substances That Would be Considered Poisonous or Deleterious Under Extreme Conditions but That Do Not Represent a Reasonable Possibility of Harm to Human Health Under Actual Conditions of Human Use.

Throughout history, the food supply has always consisted of natural food items and of functional ingredients added in the course of food production and processing. As part of the industrial revolution, our large urban centers developed, and people no longer grew their own food. Dramatic changes were needed in food production, transportation, processing, packaging, and preservation in order to accommodate this new national lifestyle. Society increasingly depended upon chemicals of both natural and synthetic origin to serve these purposes, and the number and frequency of these substances in the food supply—both as functional additives and as environmental contaminants—therefore inevitably increased. Our food supply has been estimated to consist of more than 13,000 known direct and indirect constituents and an untold number of additional environmental contaminants.[36]

Although these added substances have always been present, they have not always been detectable by the scientific methodology available to analytical chemists. At the beginning of this century, for example, when the 1906 Act was enacted, analytical methodology was basically qualitative rather than quantitative in nature and in some re-

[36]"Food Additives: Competitive, Regulatory, and Safety Problems," Hearings before the Select Committee on Small Business, United States Senate, 95th Cong., 1st Sess. 42, 52, 57, 502-503 (1977).

spects had advanced very little beyond what was known and practiced in ancient Greece and Rome.[37] By the time that the 1938 Act was passed, analytical methodology had become more quantitative in nature, but was accurate only at relatively high levels. When the Food Additives Amendment of 1958[38] was enacted, the sensitivity of detection methodology had been reduced to the relatively high parts per million (ppm) level. During the past 30 years, it has progressively been reduced first to the very low ppm level, then to parts per billion (ppb) and parts per trillion (ppt), and now to parts per quadrillion (ppq).[39] In a preamble to a proposed regulation published by FDA in 1979, the agency described this:

> ". . . trend of the increasing capacity of analytical chemistry to detect [and] measure the presence of chemicals. Depending on the substance or class of substances this decrease in the lowest limits of measurement during the last 20 years ranges between two and five orders of magnitude [*i.e.*, between 100 and 100,000 times]."[40]

It is helpful, in appreciating the significance of these levels, to realize that one ppb, which is now commonplace for all detection methodology, is equivalent to one second in 32 years or one inch in 16,000 miles.

With every incremental advance in the science of analytical chemistry, more and more added substances have

[37]Browne, "Adulteration and the Condition of Analytical Chemistry Among the Ancients," 29 Science 455 (March 19, 1909). Dr. Browne served as President of the Association of Official Analytical Chemists in 1925 and as Commissioner of Food and Drugs during 1923-1927.

[38]72 Stat. 1784 (1958).

[39]*E.g.*, Richardson et al., Sub-Part-Per-Trillion Detection of Riboflavin by Laser-Induced Fluorescence, 86 Analytica Chimica Acta 263 (1976).

[40]44 Fed. Reg. 17070, 17075 (March 20, 1979). The notice included tables showing the increased sensitivity of the analytical detection methodology for specific chemicals. *Id.* at 17076-17077.

been found at trace levels in the American food supply. Most, if not all, of these added substances would be regarded as poisonous or deleterious under extreme conditions of use, but pose no reasonable possibility of harm to human health under their actual conditions of use. Poisonous or deleterious substances that could not be found at the ppm level can often be found at the ppb or ppt level, and are even more certain to be found at the ppq level. Although it appeared in 1938, when Section 406 was enacted, that there were relatively few added poisonous or deleterious substances to be found in food, it is now apparent that there are literally hundreds of them.

For example, FDA now recognizes that carcinogens are ubiquitous in our environment and that it is impossible to attain a carcinogen-free supply of food. As early as 1971, FDA stated that carcinogenic estrogens occur naturally in many raw agricultural commodities.[41] In 1979, FDA determined that a cancer warning on the label of all food containing a carcinogen might be "impractical and confusing" because:

> ". . . a requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant (in contrast to a deliberately added carcinogenic substance) would apply to many, perhaps most, foods in a supermarket."[42]

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[41] "Regulation of Diethylstilbestrol (DES)," Hearings before a Subcommittee of the Committee on Government Operations, House of Representatives, 92d Cong., 1st Sess., Pts 1 & 2 (1972).

[42] 44 Fed. Reg. 59509, 59513 (October 16, 1979). Officials of the FDA's Center for Food Safety and Applied Nutrition, writing about the added carcinogenic substances in food, have noted "the carcinogenic hazards from corn, peanuts, milk, grain, canned food, hamburger, poultry, beef, fish, hot dogs, and even scotch and beer" and have stated that "the spectrum of natural carcinogenic contaminants at low levels in food" is very large. Scheuplein et al., New Approaches to the Regulation of Carcinogens in Food: The Food and Drug Administration, *in* H.A. Millman & E.K. Weisburger, Handbook of Carcinogen Testing 556, 561, 565 (1985).

As one example, the National Toxicology Program of the Department of HHS announced in 1983 that allyl isothiocyanate, which was shown to be a carcinogen, is:

> ". . . the major component in volatile oil of mustard, a flavoring agent prepared from seed of black mustard.
>
> Allyl isothiocyanate may be present in syrups, meats, condiments, baked goods, candy, ice cream and ices, and non-alcoholic beverages. Allyl isothiocyanate is found in cabbage, broccoli, kale, cauliflower and horseradish."[43]

Numerous dietary carcinogens in the natural food supply—including herbs, spices, and essential vitamins and minerals—have been identified in the scientific literature.[44] None of these can be disregarded by FDA either as not added or as not poisonous or deleterious.

C. FDA Has Rationally and Reasonably Applied the Statute to Regulate Added Poisonous or Deleterious Substances.

Were it not for the statutory interpretation of the food safety provisions of the FD&C Act adopted and consistently applied by FDA, this would have become a regulatory nightmare for FDA, the food industry, and the public. As more and more added poisonous or deleterious substances are found, reasonable decisions must be made by FDA on how best to handle them in order to assure a safe food supply for the American public.

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[43] 48 Fed. Reg. 4557 (February 1, 1983).

[44] *E.g.*, Ames, Dietary Carcinogens and Anticarcinogens, 221 Science 1256 (September 23, 1983); Campbell, Web of Hunger: More is Not Necessarily Better, 90 Natural History, no. 5, at 12 (May 1981); Miller et al., eds., Naturally Occurring Carcinogens-Mutagens and Modulators of Carcinogenesis (1979); Rodricks & Pohland, Food Hazards of Natural Origin, *in* H. Roberts, ed., Food Safety 181 (1981); National Academy of Sciences, Toxicants Occurring Naturally in Food (2d ed. 1973); Weisburger, Carcinogenic Natural Products, *in* Food and Drug Administration, Symposium on Structural Correlates of Carcinogenesis and Mutagenesis 184 (1977).

Until the early 1970s, the potential magnitude of this problem was not appreciated. By 1974, FDA realized that it could no longer ignore the growing number of added poisonous or deleterious substances that are required or unavoidable in the food supply, and thus for the first time proposed procedural regulations to implement Section 406.[45] In the explanatory preamble, FDA first set out the expansive interpretation of the term "added" that it has always espoused. The preamble concluded that enactment of the Food Additives Amendment of 1958 neither explicitly nor implicitly excluded food additives from the scope of Section 406:

> "When the Food Additives Amendment of 1958 was enacted, the provisions of section 406 of the act were not repealed. Although all added poisonous or deleterious ingredients are food additives, except when they appear in food accidentally and unforeseeably or are exempted under section 201(s) of the act because they are otherwise regulated under the act, the tolerance-setting provisions of section 406 of the act were left intact to deal with those unavoidably added poisonous or deleterious ingredients that could not meet the high standards for issuance of a regulation under the authority of section 409 of the act."[46]

As FDA recognized, a number of food additives that cannot meet the "high standards" of Section 409 might nonetheless be required or unavoidable in food.[47]

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[45]39 Fed. Reg. 42743 (December 6, 1974).

[46]*Id.* at 42744.

[47]The safety standards in Section 402(a)(1) and Section 409 are indistinguishable. Section 402(a)(1) has been interpreted by this Court to embody the standard of a "reasonable possibility of harm." Section 409, as explained in the legislative history that has been adopted by FDA as the definitive statement of the 1958 Amendment, embodies a standard of "reasonable certainty [of] no harm." H.R. Rep. No. 2284, 85th Cong., 2d Sess. 4 (1958). The 1958 Amendment thus transfered the burden of proving safety from the government to the regulated industry, but did not change the safety standard itself.

In response to the proposed regulation, FDA received one comment questioning the authority for Section 406 tolerances for food additives under the "cannot be avoided" portion of Section 406. The preamble to the final regulations,[48] promulgated in 1977, agreed that an intentional food additive was usually avoidable, but did not agree that such an additive could not meet the "required in the production" portion of Section 406. FDA emphasized the distinction between these two portions of Section 406 in rejecting a comment that had argued that the term "added" should be narrowly interpreted to apply only to human activity:

> "The Commissioner notes that the comment discussed only the initial portion of section 406 of the act. The section goes on to identify two circumstances in which 'added' poisonous or deleterious substances may be permitted: (1) Where the substance is 'required in the production' of a food, and (2) or where the substance 'cannot be avoided by good manufacturing practice.' Although the language of the first circumstance connotes human action, the language of the second does not."[49]

The final regulations promulgated by FDA in 1977 explicitly dealt only with added poisonous or deleterious substances that fall within the "cannot be avoided" portion of Section 406, and did not deal at all with those that fall within the "required in the production" portion of Section 406.[50] Similarly, the instant case involves only the former and not the latter. In 1979, FDA determined that a deliberately added poisonous or deleterious substance (lead

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[48]42 Fed. Reg. 52814 (September 30, 1977).

[49]*Id.*

[50]21 C.F.R. pt 109.

in food canning) could be encompassed within the "required in the production" portion of Section 406.[51]

Under the FDA regulatory approach that has prevailed for the past half century, control of all added poisonous or deleterious substances has proved to be a manageable task. For those added poisonous or deleterious substances that represent an insignificant risk—whether they are "required in the production" of food or "cannot be avoided"—FDA simply ignores their presence and does not establish either an informal action level or a formal tolerance. For those that are required in food production and that are found at levels that could potentially raise public health concern, regulatory controls under Sections 402(a)(1), 408, and 409 have been sufficient to protect the public health. For those that are unavoidable and that are found at levels that could potentially raise public health concern, action levels (shown in Appendix A) have been established to make certain that they represent no reasonable possibility of harm to human health. As more has become known about those substances (and their toxicity and level of human exposure), those action levels have been changed over time. In the one instance where sufficient data have accumulated to permit a permanent maximum level, and persistent litigation justified the time and expense involved in the administrative proceeding, a formal tolerance has been promulgated on the basis of a rulemaking on a record.[52]

This approach is sensible and has in fact worked very well to protect the health of the American public. FDA has established conservative levels for added poisonous or deleterious substances and in fact no human toxicity has been traced to them.

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[51] 44 Fed. Reg. 51233, 51240 (August 31, 1979).

[52] 21 C.F.R. § 109.30 (polychlorinated biphenyls).

III. The Decision of the Court of Appeals Would Impose a Burdensome and Unreasonable Regulatory Scheme Without Any Public Health Benefit.

In place of the existing common sense approach that has prevailed for the past 50 years, the court of appeals would arbitrarily require an expensive and time-consuming new scheme that would serve no public health purpose. The novel interpretation advanced by the court of appeals would require the formal establishment of a tolerance under Section 406, based upon rulemaking on a record, for every added poisonous or deleterious substance found in the food supply. At the outset, this would encompass all of the substances, and all of the uses specified, in the current FDA action levels reprinted in Appendix A.

This would, however, only be the beginning. Many of the poisonous or deleterious substances listed in Appendix A can readily be found, under modern methods of analytical chemistry, in other foods as well. And as analytical methods become increasingly more sensitive, they will be found in still other food products.

Nor would this be the end of the matter. There are hundreds of other added poisonous or deleterious substances presently found in the food supply, under sensitive detection methodology, which present such an insignificant risk that FDA has not bothered to list them or to establish an action level. Under the extreme interpretation of the court of appeals, however, FDA would be required to establish a formal tolerance even for these substances, to avoid the food becoming unlawful *per se*.

Nor would even this finish the job. Dozens of natural food substances can be found, under extreme conditions of laboratory testing, to be carcinogenic, teratogenic,. or otherwise to produce toxic results. FDA presently concludes that the use of these substances should not be banned under Section 402(a)(1) and need not be limited under Section 406. The court of appeals would require a lengthy rulemaking for each.

All of this would be required solely in the name of strict statutory construction, with no attention paid to the overall statutory structure or to the protection of the public health. Scarce agency and industry resources would be channeled away from productive enterprise into formal rulemaking proceedings designed solely to satisfy procedural requirements. Formal rulemaking on a record, which is subject to the strict requirements for adjudication under the Administrative Procedure Act,[53] is resource-intensive and imposes substantial burdens upon FDA and the regulated industry.[54] There has been, and can be, no suggestion that any of these proceedings would advance public health objectives.

To the extent that any person believes that a current FDA action level is too high (or too low), or that a particular poisonous or deleterious substance that currently has no action level should in fact be regulated through an action level, procedural remedies are presently available. FDA has promulgated regulations establishing the right of any person to petition FDA for appropriate action under these circumstances.[55] There is no need to establish an entire new regulatory scheme in order to assure adequate protection both of the procedural rights of interested persons and of the substantive right to a safe food supply.

IV. The Decision of the Court of Appeals Conflicts With Two Authoritative Supreme Court Decisions.

The decision of the court of appeals in this case is fundamentally in conflict with two major Supreme Court de-

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[53]5 U.S.C. § 556 and § 557.

[54]*See, e.g.*, Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 Tex. L. Rev. 1132 (1972). The enormous administrative burden that would have been imposed by the requirement of hundreds of such formal administrative hearings was one factor that led this Court to conclude that the FD&C Act should not be interpreted to incorporate such a requirement for all new drug application withdrawals in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 621 (1973).

[55]21 C.F.R. § 109.5 and § 10.30.

cisions, one of which was decided less than a week after the decision by the court of appeals in this case.

A. The Lexington Mill Decision Establishes FDA's Court Enforcement Authority Under Section 402(a)(1).

As noted above, the prohibition against added poisonous or deleterious substances under the 1906 Act, as interpreted by this Court in the *Lexington Mill* case in 1914, was explicitly retained by Congress under the 1938 Act.[56] Thus, Congress intended FDA to continue to exercise its administrative enforcement discretion to determine whether it was reasonably possible that an added poisonous or deleterious substance would render food injurious to health under actual conditions of use. There is no legislative history to support the view, advanced by the court of appeals, that enactment of Section 406 qualified or overruled this independent court enforcement authority.[57]

B. The Decision in *Heckler* v. *Chaney* Establishes That An FDA Administrative Determination Not To Initiate Court Enforcement Action Is Ordinarily Unreviewable In The Courts.

Just six days after the court of appeals handed down its decision in the instant case, the Supreme Court handed

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[56]Notes 12-14 *supra* and accompanying text.

[57]This Court has, in an analogous context, recognized that FDA has been given two independent methods of enforcing a common statutory objective—administrative rulemaking proceedings and direct action in the courts. In Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973), and CIBA Corp. v. Weinberger, 412 U.S. 640, 643-644 (1973), the Court held that FDA has primary jurisdiction to decide with administrative finality the regulatory status of products within its jurisdiction and, at the same time, independently has administrative discretion to initiate enforcement action directly in the courts. The CIBA decision explicitly recognized the power of FDA to initiate court enforcement action without first undertaking an administrative proceeding. The same logic applies here as well. Thus, the provisions of Section 406, relating to administrative proceedings, should in no way interfere with the provisions of Section 402(a)(1) authorizing court enforcement proceedings.

down its decision in *Heckler* v. *Chaney*.[58] It is apparent that the decision of the court of appeals is in serious conflict with the *Chaney* decision.

In *Chaney*, the Court held that an FDA decision not to initiate court enforcement action is ordinarily unreviewable in the courts. Absent fraud or other extraordinary circumstances, enforcement decisions are "committed to agency discretion" under the Administrative Procedure Act. In its opinion, the Court explained some of the "administrative concerns" which underlie this policy.[59] These "administrative concerns" describe, of course, the very reasons why FDA enforcement of the food safety provisions of the law must remain within the scope of administrative discretion.

The decision of the court of appeals, however, takes the matter entirely out of FDA's administrative discretion and requires the agency to establish formal tolerances, through rulemaking on a record, for each and every poisonous or deleterious substance found in the food supply. Under the interpretation adopted by the court of appeals, FDA's deployment of resources, and ordering of priorities, would be dictated by procedures imposed by the judiciary and not by public health concerns. They would be required for purely procedural rather than substantive reasons. The approach adopted by the court of appeals is thus irreconcilable with the approach of this Court in *Chaney*.

Even if formal tolerances were adopted for all poisonous or deleterious substances under Section 406, the *Chaney* decision would make them a procedural nicety and a substantive nullity. Enforcement priorities would remain discretionary with FDA regardless of the procedure imposed upon FDA in establishing unacceptable levels of poisonous or deleterious substances in the food supply. It makes little sense to reorder FDA's priorities, and to abrogate a well-established food safety regulatory program that has stood

[58]Heckler v. Chaney, 105 S. Ct. 1649 (1985).

[59]*Id.* at 1656.

the test of 50 years of experience, when the end result will be no different than it is now.

V. The Decision of the Court of Appeals Would Automatically Render the Vast Bulk of the American Food Supply Unlawful for the Foreseeable Future.

The action levels that would be invalidated by the court of appeals, as shown in Appendix A, pertain to a substantial portion of this country's food supply. Under the novel interpretation adopted by the court of appeals, all of the food covered by those action levels would instantly become adulterated and thus illegal *per se* under the FD&C Act. Equally important, all other foods which contain added poisonous or deleterious substances that FDA has determined to present only an insignificant risk, and thus do not justify even an action level, would be equally unlawful. With the extraordinary sensitivity of detection methodology now available to analytical chemists, it is difficult to imagine many foods, if any, that would escape this broad condemnation.

Even with heroic efforts and the deployment of a substantial portion of FDA personnel, it is unlikely that administrative proceedings could be initiated and completed for all of these added poisonous or deleterious substances in all of the myriad foods that comprise our national diet.[60] It is likely that, as soon as one proceeding was completed, other added poisonous or deleterious substances would be detected in still other foods. It is thus questionable whether FDA could ever catch up with the problem, or would forever be chasing an unachievable administrative goal.

This regulatory dilemma only serves to underscore the impractical and unrealistic interpretation adopted by the court of appeals, and the sound policy reasons for the consistent administrative interpretation adopted by FDA of these provisions for the past 50 years. As this Court has recognized, the FD&C Act "is to be treated as a working instrument of government and not merely as a

[60]Note 54 *supra*.

collection of English words"[61] and thus must be given "a liberal construction consistent with the Act's overriding purpose to protect the public health."[62] A formalistic requirement of rigid Section 406 tolerances, after rulemaking on a record, will achieve no such purpose.

It is no comfort to the food industry that, under the *Chaney* decision, FDA undoubtedly would exercise its inherent administrative discretion not to initiate court enforcement action against the entire food supply or even those foods for which action levels have been established as shown in Appendix A. There are serious commercial implications that could flow from the decision of the court of appeals as well. Under the Uniform Commercial Code, food is sold subject to the implied warranties of merchantability and fitness for the intended purpose.[63] Food that is in violation of federal law could readily be regarded as in violation of these implied warranties. Accordingly, the decision by the court of appeals could jeopardize virtually all commercial transactions in the food industry. Those who sought a way to abrogate contracts for the sale of food would need to look no further than the decision of the court of appeals in the instant case.

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[61]United States v. Dotterweich, 320 U.S. 277, 280 (1943).

[62]United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969).

[63]Uniform Commercial Code § 2-314 and § 2-315.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be reversed.

Respectfully submitted,

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APPENDIX A

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

Action levels for poisonous or deleterious substances are established by the Food and Drug Administration (FDA) to control levels of contaminants in human food and animal feed.

The action levels are established and revised according to criteria specified in Title 21, *Code of Federal Regulations*, Parts 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective.

Action levels and tolerances represent limits at or above which FDA will take legal action to remove adulterated products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant.

Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable. The blending of a food or feed containing a substance in excess of an action level or tolerance with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

This booklet lists action levels established by the FDA for poisonous or deleterious substances in human food and animal feed. This list is current as of September, 1982. Notices will be published in the *Federal Register* as new action levels are established or as existing action levels are revised or revoked. It is the responsibility of the user of the list to keep up to date on changes in the action levels.

Single *copies* of this booklet are available from:

Food and Drug Administration
Industry Programs Branch
Bureau of Foods (HFF-326)
200 C Street, S.W.
Washington, D.C. 20204
Phone (202) 245-1523

Copies of the *Compliance Policy Guides* (CPG) referenced in the action level list may be obtained from:

Food and Drug Administration
Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857
Phone (301) 443-6310

Other *references* in the action level list are filed under Docket No. 77N-0166 for public viewing at:

Food and Drug Administration
Docket's Management Branch (HFA-305)
5600 Fishers Lane
Rockville, Maryland 20857
Phone (301) 443-1753

For further *assistance or information* contact:

Food and Drug Administration
Guidelines and Compliance Research Branch
Bureau of Foods (HFF-312)
200 C Street, S.W.
Washington, D.C. 20204
Phone (202) 245-3092

FDA ACTION LEVELS
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FDA ACTION LEVELS

AFLATOXIN

Commodity	Action Level	Reference
Brazil nuts	20.0 mcgs/kg	CPG 7112.07
Feeds and feed ingredients	20.0 ppb	CPG 7126.33
Foods	20.0 mcgs/kg	CPG 7120.26
Milk	0.5 ppb (aflatoxin M_1)	CPG 7106.10
Peanuts & peanut products	20.0 mcgs/kg	CPG 7112.02
Pistachio nuts	20.0 mcgs/kg	CPG 7112.08

ALDRIN & DIELDRIN

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at a level below 0.03 ppm for nonfatty foods and 0.3 ppm for fish and for milk.

Commodity	Action Level	Reference
Animal feed, finished, processed	0.03 ppm	CPG 7126.27-A
Artichokes	0.05 ppm	CPG 7120.23-A
Eggs	0.03 ppm	CPG 7120.23-A
Fats & oils: animal, vegetable fish (animal feed)	0.3 ppm	CPG 7126.27-A
Fish and shellfish	0.3 ppm	CPG 7120.23-A
Figs	0.05 ppm	CPG 7120.23-A
Hay (animal feed)	0.03 ppm	CPG 7126.27-A

Melons[1]	0.15 ppm	CPG 7120.23-A
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-A
Small fruits[1,2]	0.05 ppm	CPG 7120.23-A
Sugarbeet pulp (animal feed)	0.1 ppm	CPG 7126.27-A

[1]Other than those commodities specified in 40 C.F.R 180.135 and 180.137.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

BENZENE HEXACHLORIDE (BHC)

The figures below are for residues of total BHC. However, in adding amounts of individual isomers do not count alpha, gamma or delta BHC at a level below 0.1 ppm in milk or eggs and below 0.02 in other products. Do not count beta BHC at a level below 0.2 in milk or eggs and below 0.04 in other products.

Commodity	Action Level	Reference
Animal feed, processed	0.1 ppm	CPG 7126.27-B
Barley, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Barley, grain (human food)	0.1 ppm	CPG 7120.23-B
Beans	0.5 ppm	CPG 7120.23-B
Citrus fruit[2]	0.5 ppm	CPG 7120.23-B
Cocoa beans, whole raw bean	0.5 ppm	CPG 7120.23-B
Corn, fresh sweet	0.5 ppm	CPG 7120.23-B
Corn, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Corn, grain (human food)	0.1 ppm	CPG 7120.23-B
Eggs	0.5 ppm	CPG 7120.23-B
Endive	0.5 ppm	CPG 7120.23-B
Figs	0.5 ppm	CPG 7120.23-B
Frog legs	0.5 ppm	CPG 7120.23-B
Guavas	0.5 ppm	CPG 7120.23-B
Hays (animal feed)	0.1 ppm	CPG 7126.27-B
Mangoes	0.5 ppm	CPG 7120.23-B
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-B
Milo, sorghums (animal feed)	0.1 ppm	CPG 7126.27-B
Milo, sorghums (human food)	0.1 ppm	CPG 7120.23-B
Oats, grain (animal feed)	0.1 ppm	CPG 7126.27-B

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Oats, grain (human food)	0.1 ppm	CPG 7120.23-B
Peas	0.5 ppm	CPG 7120.23-B
Pineapples	0.5 ppm	CPG 7120.23-B
Quinces	0.5 ppm	CPG 7120.23-B
Root vegetables[2]	0.5 ppm	CPG 7120.23-B
Rice, grain	0.1 ppm	CPG 7120.23-B
Rye, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Rye, grain (human food)	0.1 ppm	CPG 7120.23-B
Small fruits[1],[2]	0.5 ppm	CPG 7120.23-B
Turnip greens	0.5 ppm	CPG 7120.23-B
Wheat, grain (animal feed)	0.1 ppm	CPG 7126.27-B
Wheat, grain (human food)	0.1 ppm	CPG 7120.23-B

[1]Other than those commodities specified in 40 C.F.R. 180.146.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

CADMIUM

Commodity	Action Level	Reference
Pottery(ceramics)		CPG 7117.06
Flatware (ave. of 6 units)	0.5 mcgs/ml of leaching solution	
Small hollowware (any one of 6 units)	0.5 mcgs/ml of leaching solution	CPG 7117.06
Large hollowware (any one of 6 units)	0.25 mcgs/ml of leaching solution	CPG 7117.06

CHLORDANE

Commodity	Action Level	Reference
Animal fat, rendered	0.8 ppm	CPG 7126.27-C
Animal feed	0.1 ppm	CPG 7126.27-C
Fish	0.3 ppm	CPG 7120.23-C

CROTALARIA SEEDS
(C. spectabilis and/or C. sagittalis and/or C. striata)

Commodity	Action Level	Reference
Grains and Feeds	Average of 1 whole seed/pound	CPG 7126.15

FDA ACTION LEVELS

DIBROMOCHLOROPROPANE (DBCP)

Commodity	Action Level	Reference
Milk	1.5 ppm (fat basis)	CPG 7120.23-E
Raw agricultural commodities (except milk)	0.05 ppm	CPG 7120.23-E

DDT, DDE, AND TDE

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of DDT, DDE and TDE do not count any of the three found below 0.2 ppm for fish, eggs, and grain.

Commodity	Action Level	Reference
Animal feed, processed	0.5 ppm	CPG 7126.27-D
Barley, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Barley, grain (human food)	0.5 ppm	CPG 7120.23-D
Cocoa beans, whole raw bean	2.0 ppm	CPG 7120.23-D
Corn, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Corn, grain (human food)	0.5 ppm	CPG 7120.23-D
Eggs	1.5 ppm	CPG 7120.23-D
Fish	5.0 ppm	CPG 7120.23-D
Hay	0.5 ppm	CPG 7126.27-D
Milo (sorghum), grain (animal feed)	0.5 ppm	CPG 7126.27-D
Milo (sorghum), grain (human food)	0.5 ppm	CPG 7120.23-D
Oats, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Oats, grain (human food)	0.5 ppm	CPG 7120.23-D
Rice, grain (animal feed)	0.5 ppm	CPG 7126.27-D

Rice, grain (human food)	0.5 ppm	CPG 7120.23-D
Rye, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Rye, grain (human food)	0.5 ppm	CPG 7120.23-D
Wheat, grain (animal feed)	0.5 ppm	CPG 7126.27-D
Wheat, grain (human food)	0.5 ppm	CPG 7120.23-D

FDA ACTION LEVELS

ENDRIN

Commodity	Action Level	Reference
Animal feed, processed	0.03 ppm	CPG 7126.27-E
Asparagus	0.05 ppm	CPG 7120.23-F
Beans	0.05 ppm	CPG 7120.23-F
Citrus fruits[2]	0.05 ppm	CPG 7120.23-F
Corn, fresh sweet	0.05 ppm	CPG 7120.23-F
Eggs	0.03 ppm	CPG 7120.23-F
Figs	0.05 ppm	CPG 7120.23-F
Fish and shellfish	0.3 ppm	CPG 7120.23-F
Fish meal, fish solubles, fish oil (animal feed)	0.3 ppm	CPG 7126.27-E
Guavas	0.05 ppm	CPG 7120.23-F
Leafy vegetables[1],[2]	0.05 ppm	CPG 7120.23-F
Mangoes	0.05 ppm	CPG 7120.23-F
Melons	0.05 ppm	CPG 7120.23-F
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-F
Oilseed meal-peanut, soybean, cottonseed, etc. (animal feed)	0.03 ppm	CPG 7126.27-E
Okra	0.05 ppm	CPG 7120.23-F
Peas	0.05 ppm	CPG 7120.23-F
Pimentoes	0.05 ppm	CPG 7120.23-F
Pineapples	0.05 ppm	CPG 7120.23-F
Pome fruits[2]	0.05 ppm	CPG 7120.23-F
Pumpkins	0.05 ppm	CPG 7120.23-F
Root vegetables[1],[2]	0.05 ppm	CPG 7120.23-F
Small fruits[2]	0.05 ppm	CPG 7120.23-F
Stone fruits[2]	0.05 ppm	CPG 7120.23-F

[1]Other than those commodities specified in 40 C.F.R. 180.131.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Vegetable oils and fats, including soapstock (animal feed)	0.3 ppm	CPG 7126.27-E

FDA ACTION LEVELS

FENTHION

Commodity	Action Level	Reference
Ground red peppers	0.3 ppm	CPG 7120.23-G

FDA ACTION LEVELS

HEPTACHLOR AND HEPTACHLOR EPOXIDE

The figures below are for residues of the above pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found at a level below 0.3 ppm for fish and 0.03 ppm for other products.

Commodity	Action Level	Reference
Animal feed, processed	0.03 ppm	CPG 7126.27-F
Artichokes	0.05 ppm	CPG 7120.23-H
Asparagus	0.05 ppm	CPG 7120.23-H
Beans, except snap beans	0.05 ppm	CPG 7120.23-H
Citrus fruits[2]	0.05 ppm	CPG 7120.23-H
Cucumbers	0.05 ppm	CPG 7120.23-H
Dairy products (manufactured)[1]	0.1 ppm	CPG 7120.23-H
Eggs	0.03 ppm	CPG 7120.23-H
Eggplant	0.05 ppm	CPG 7120.23-H
Figs	0.05 ppm	CPG 7120.23-H
Fish and shellfish	0.3 ppm	CPG 7120.23-H
Leafy vegetables	0.05 ppm	CPG 7120.23-H
Hays[1]	0.03 ppm	CPG 7126.27-F
Melons	0.05 ppm	CPG 7120.23-H
Okra	0.05 ppm	CPG 7120.23-H
Pears	0.05 ppm	CPG 7120.23-H
Pimentoes	0.05 ppm	CPG 7120.23-H
Pumpkins	0.05 ppm	CPG 7120.23-H
Quinces	0.05 ppm	CPG 7120.23-H
Rice, grain, (animal feed)	0.03 ppm	CPG 7126.27-F
Rice, grain (human food)	0.03 ppm	CPG 7120.23-H
Small fruits[1],[2]	0.05 ppm	CPG 7120.23-H

[1]Other than those commodities specified in 40 C.F.R. 180.104 and 180.319.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Stone fruits[1],[2]	0.05 ppm	CPG 7120.23-H
Squash (summer or winter)	0.05 ppm	CPG 7120.23-H

[1]Other than those commodities specified in 40 C.F.R. 180.104 and 180.319.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

KELTHANE
[1,1 Bis (p-chlorophenyl)-2,2,2-trichloroethanol]

Commodity	Action Level	Reference
Animal feed, finished processed	0.5 ppm	CPG 7126.27-H

KEPONE
[Decachlorooctahydro-1,3,4-methano-2H-cyclobuta (cd) pentalen-2-one]

Commodity	Action Level	Reference
Crabmeat	0.4 ppm	CPG 7120.23-I
Fish	0.3 ppm	CPG 7120.23-I
Shellfish	0.3 ppm	CPG 7120.23-I

FDA ACTION LEVELS

LEAD

Commodity	Action Level	Reference
Pottery (ceramics)		CPG 7117.07
Flatware (ave. of 6 units)	7.0 mcgs/ml of leaching solution	
Small hollowware (any one of 6 units)	5.0 mcgs/ml of leaching solution	CPG 7117.07
Large hollowware (any one of 6 units)	2.5 mcgs/ml of leaching solution	CPG 7117.07
Silver-plated hollowware (ave. of 6 units)	7.0 mcgs/ml of leaching solution if product intended for use by adults	CPG 7117.05
Silver-plated hollowware (one or more of 6 units)	0.5 mcgs/ml of leaching solution if product intended for use by infants and children	CPG 7117.05

FDA ACTION LEVELS

LINDANE

Commodity	Action Level	Reference
Animal feed, processed	0.1 ppm	CPG 7126.27-H
Artichokes	0.5 ppm	CPG 7120.23-J
Barley, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Barley (human food)	0.1 ppm	CPG 7120.23-J
Beans	0.5 ppm	CPG 7120.23-J
Citrus fruit[2]	0.5 ppm	CPG 7120.23-J
Cocoa beans, whole raw bean	0.5 ppm	CPG 7120.23-J
Corn, fresh sweet	0.5 ppm	CPG 7120.23-J
Corn, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Corn, grain (human food)	0.1 ppm	CPG 7120.23-J
Eggs	0.5 ppm	CPG 7120.23-J
Endive	0.5 ppm	CPG 7120.23-J
Figs	0.5 ppm	CPG 7120.23-J
Hays	0.1 ppm	CPG 7126.27-H
Milk and dairy products	0.3 ppm (fat basis)	CPG 7120.23-J
Milo (sorghum), grain (animal feed)	0.1 ppm	CPG 7126.27-H
Milo (sorghum), grain, (human food)	0.1 ppm	CPG 7120.23-J
Oats, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Oats, grain (human food)	0.1 ppm	CPG 7120.23-J
Peas	0.5 ppm	CPG 7120.23-J
Rice, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Rice, grain (human food)	0.1 ppm	CPG 7120.23-J
Root vegetables[1],[2]	0.5 ppm	CPG 7120.23-J
Rye, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Rye, grain (human food)	0.1 ppm	CPG 7120.23-J

[1]Other than those commodities specified in 40 C.F.R. 180.133.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Small fruits[1],[2]	0.5 ppm	CPG 7120.23-J
Turnip greens	0.5 ppm	CPG 7120.23-J
Wheat, grain (animal feed)	0.1 ppm	CPG 7126.27-H
Wheat, grain (human food)	0.1 ppm	CPG 7120.23-J

[1]Other than those commodities specified in 40 C.F.R. 180.133.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

FDA ACTION LEVELS

MERCURY

Commodity	Action Level	Reference
Fish, shellfish, crustaceans, other aquatic animals. Edible portion only. Fresh, frozen or processed.	1.0 ppm	CPG 7108.07
Wheat (pink kernals only)	1.0 ppm	CPG 7104.05

METHYL ALCOHOL

Commodity	Action Level	Reference
Imported brandy	0.35%	CPG 7119.09

MIREX

Commodity	Action Level	Reference
Fish	0.1 ppm	CPG 7120.23-K

NITROSODIMETHYLAMINE (NDMA)

Commodity	Action Level	Reference
Barley Malt	10 ppb	CPG 7104.07
Malt Beverages	5 ppb	CPG 7101.07

FDA ACTION LEVELS

PARALYTIC SHELLFISH TOXIN

Commodity	Action Level	Reference
Clams (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20
Mussels (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20
Oysters (fresh, frozen, canned)	80 mcg/100 g meat	CPG 7108.20

POLYBROMINATED BIPHENYLS (PBB's)

Commodity	Action Level	Reference
Milk & dairy products (fat basis)	0.3 ppm	"A Review of Congressman William M. Brodhead's Petition to Reduce FDA Action Levels for Polybrominated Biphenyls (PBB) in Food", July 27, 1977
Meat (fat basis)	0.3 ppm	
Eggs	0.05 ppm	
Animal Feed	0.05 ppm	

FDA ACTION LEVELS

POLYCHLORINATED BIPHENYLS (PCB's)

Commodity	Action Level	Reference
Paper food-packaging material intended for or used with human food, finished animal feed and components intended for animal feeds	10 ppm	21 CFR 109.30 (a)(9) and 509.30 (a)(9) Tolerance stayed on 8-24-73 (38 FR 22794) 21 CFR 109.6(d) and 509.6(d)
Red Meat	3 ppm (fat basis)	CPG 7111.03

TOXAPHENE

Commodity	Action Level	Reference
Animal feed, processed	0.5 ppm	CPG 7126.27-I
Artichokes	1.0 ppm	CPG 7120.23-L
Asparagus	1.0 ppm	CPG 7120.23-L
Cherries	1.0 ppm	CPG 7120.23-L
Figs	1.0 ppm	CPG 7120.23-L
Fish	5.0 ppm	CPG 7120.23-L
Melons	1.0 ppm	CPG 7120.23-L
Mustard greens	1.0 ppm	CPG 7120.23-L
Plums	1.0 ppm	CPG 7120.23-L
Pumpkins	1.0 ppm	CPG 7120.23-L
Root vegetables[1],[2]	1.0 ppm	CPG 7120.23-L
Small fruits[1],[2]	1.0 ppm	CPG 7120.23-L

[1]Other than those commodities specified in 40 C.F.R. 180.138.

[2]Refer to 40 C.F.R. 180.34(f) for commodities covered by this food group.

Squash (summer or winter)	1.0 ppm	CPG 7120.23-L
Turnip greens	1.0 ppm	CPG 7120.23-L

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No. 85-664

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

**On Writ Of Certiorari To
The United States Court of Appeals
For The District Of Columbia Circuit**

BRIEF OF AMERICAN FEED INDUSTRY ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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BRIEF OF AMERICAN FEED INDUSTRY ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

STATEMENT OF INTEREST OF THE AMICUS CURIAE

Amicus, the American Feed Industry Association (AFIA), submits this brief in support of the Petitioner Frank Young, Commissioner of Food and Drugs. Consent to file this brief has been obtained from counsel

for all parties and has been filed with the Clerk of this Court.

AFIA is the national trade association representing manufacturers and distributors of animal feeds, feed ingredients, and animal drugs. AFIA members include private companies and cooperatives and range from large corporations to small local establishments. They include manufacturers of animal feeds, producers of feed ingredients, manufacturers of animal drugs, and blenders and distributors of animal health products.

AFIA's members are among the largest purchasers of U.S. agricultural commodities, such as corn, which are used as ingredients in finished feed products. Accordingly, AFIA is greatly concerned that the raw ingredients purchased by its members to produce finished feeds and the resultant finished feeds are "safe" both as a matter of law and science. The issue of the proper regulation of environmental contaminants in food is important to the U.S. feed manufacturing industry because modern food technology has not devised a method to remove trace environmental contaminants contained in raw agricultural commodities.

The Court of Appeals decision below hinders AFIA's ability to obtain federal guidance from the U.S. Food and Drug Administration (FDA) to resolve the legal and scientific issues related to the safety of foods containing trace levels of environmental contaminants. Indeed, the decision below, if upheld, would render illegal both feed ingredients and finished feeds if either contains *any* level of a contaminant, *even if* the finished product is judged safe as a matter of science. The decision needlessly threatens to disrupt the orderly marketing of agricultural commodities, animal feeds, and, indeed, human food; needlessly because the decision is legally incorrect.

INDUSTRY RELIES ON ACTION LEVELS

Since 1972, FDA has publicly issued policy guidelines which specify the maximum levels of several environmental contaminants which would be permissible in food products without violating the food adulteration provision in the Federal Food, Drug, and Cosmetic Act (the Act) covering added poisonous and deleterious substances, Section 402(a) of the Act, 21 U.S.C. § 342(a).[1] These guidelines, customarily known as "action levels," represent the agency's opinion as to what level of contamination is necessary to prove in a federal court enforcement action that a violation of Section 402(a)(1) of the Act has occurred. In other words, FDA's action levels are used by the agency as enforcement guidelines for the application of the "may render it injurious to health" standard in Section 402(a)(1). Because action levels are based on "what may be injurious to health," they provide guidance and certainty to feed manufacturers as to those levels of contamination which are safe, as well as legal.

Feed manufacturers rely on FDA action levels since they provide reasonable assurances that if feed in-

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[1] 21 U.S.C. § 342(a)(1) provides:

> A food shall be deemed to be adulterated --
> (a)(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health. . . .

gredients fall within the established limits, they, as well as the finished feeds containing these ingredients, are safe for consumption. Feed manufacturers also rely on FDA action levels with respect to finished feeds. If their ingredients are "safe," their finished feeds may move freely and legally in interstate commerce. Thus, FDA action levels provide a dual benefit of certainty as to the safety of feed products to the consumer and as to FDA enforcement intention. The Court of Appeals decision replaces this certainty with chaos.

In the present case, FDA in 1974 had established an across the board action level of 20 parts per billion (ppb) aflatoxin for food and feed ingredients. In 1980, due to adverse weather conditions conducive to aflatoxin growth, Virginia, North Carolina, and South Carolina petitioned FDA to set a separate action level of 100 ppb aflatoxin for corn to be used strictly as an ingredient in animal feed for mature, non-lactating livestock and poultry. FDA, based on sound scientific evidence, agreed to the 100 ppb action level for corn used for these limited purposes. Moreover, the proposed distribution plan ensured the corn would not be distributed for unsafe purposes. Once FDA agreed to this action level, both the states and feed manufacturing industry knew that this corn could be safely and legally distributed for the stated purposes.

THE COURT OF APPEALS DECISION BELOW INVALIDATED ACTION LEVELS

Respondents, two public interest groups and a consumer, initially brought this action in the United States District Court for the District of Columbia challenging the procedures by which FDA approved

three state-sponsored plans for the safe distribution of corn containing innocuous levels of an unavoidable environmental contaminant, aflatoxin, a mold byproduct. The Respondents asserted that since aflatoxin is an unavoidable poisonous or deleterious substance, Section 406 of the Act, 21 U.S.C. § 346,[2] requires FDA to set maximum permissible aflatoxin levels by means of formal tolerances rather than informally by means of action levels. The District Court properly granted summary judgment in favor of FDA, holding that the agency has inherent discretion in deciding whether to proceed either by informal action levels or by tolerances pursuant to the formal rulemaking

[2]Section 406 of the Act, 21 U.S.C. § 346, provides:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

procedures set forth at Section 406 of the Act and at Section 701(e) of the Act, 21 U.S.C. § 371(e).[3]

The Court of Appeals reversed, concluding that:

> "[t]he FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1) and unsafe for the purposes of 21 U.S.C. § 342(a)(2)(A). . . ."[4]

This holding condemns, as a matter of law, any food which contains *de minimis* levels of a poisonous or deleterious substance regardless of whether the scientific evidence shows that level to pose a risk to health. As discussed below, this holding is contrary to this Court's decision in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914) and totally disrupts the orderly marketing of food products throughout the United States.

PRACTICAL EFFECT OF COURT OF APPEALS DECISION

It is impossible under current U.S. agricultural practice to avoid the presence of small quantities of field contaminants in raw agricultural commodities. These contaminants cannot be completely removed in

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[3]Section 701(e) of the Act specifies those formal administrative procedures for establishing tolerances for foods. *See infra* note 5 at 7.

[4]Petitioner's Petition for A Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit at 15A (hereafter *Pet. App.*).

processing. Thus, the Court of Appeals decision renders virtually the entire food supply adulterated as a matter of law until such time, if ever, FDA establishes formal tolerances.[5] Since this "legal" rule established by the court below totally ignores scientific evidence as to safety, feed manufacturers are left without guidance as to whether the ingredients they purchase are safe. More importantly, the decision gives feed manufacturers the Hobson's choice of either rejecting all incoming ingredients, which may present no risk to health, or breaking the law by producing technically "adulterated" and illegal animal feeds

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[5]The Court of Appeals indicated most of the practical consequences can be alleviated through the establishment of formal tolerances. *Pet. App.*, note 5 at 8a. However, this statement ignores the practicality of the situation. First, as FDA has conceded, it lacks the administrative resources to establish all necessary tolerances quickly. *Pet. App.* at 7. Section 701(e) of the Act, 21 U.S.C. § 371(e), requires the issuance of a proposed tolerance, a comment period, the issuance of a "final" tolerance, upon the receipt of a valid objection the staying of the "final" tolerance, a formal evidentiary hearing, various levels of agency "initial" and final decisions, and then appeal through the federal court system. Secondly, even if FDA had the administrative resources, formal tolerances can take years to establish. For example, it took eleven years to establish the formal tolerance for polychlorinated biphenyls (PCBs) in food and paper packaging materials, 21 C.F.R. § 109.30, even though in that formal administrative proceeding, FDA was able to avoid a full trial-type hearing which could have added years to the process. In another case, it took FDA eleven years to promulgate a standard of identity for peanut butter, 21 C.F.R. § 164.150, through the formal administrative hearing mechanism, including prompt judicial review. *See generally*, Hamilton, *Rulemaking On A Record By The Food And Drug Administration*, 50 Tex. L. Rev. 1132 (1972) and Note, *FDA Rulemaking Hearings: A Way Out Of The Peanut Butter Quagmire*, 40 Geo. Wash. L. Rev. 726 (1972).

which are safe as a matter of science. Thus, the purchasing of ingredients and the distribution of finished feed products containing traces of environmental contaminants could very well subject the feed manufacturer to lawsuits by FDA, state governments, or customers.

Under the Court of Appeals decision, FDA would have virtually no burden of proof to establish adulteration and would only be required to demonstrate in a court action that: (1) a feed ingredient or a finished feed contained any amount of a particular environmental contaminant, and (2) there is no Section 406 tolerance in effect covering that unavoidable contaminant in or on that product. Because of the ubiquitous nature of innocuous trace contamination of agricultural commodities,[6] the decision below means FDA can successfully litigate against virtually any feed manufacturer or feed product. Thus, every shipment of a contaminated ingredient or finished feed product could result in seizure and condemnation of the product, Section 304 of the Act, 21 U.S.C. § 334; and could subject the feed manufacturer to an injunction, Section 302 of the Act, 21 U.S.C. § 332, and criminal penalties including incarceration and fines of up to $100,000 per shipment, Section 303 of the Act, 21 U.S.C. § 333, and 18 U.S.C. § 3623. Even assuming FDA reasonably exercises its enforcement discretion and does not recommend that a federal court action be brought unless the amount of the contaminant in the food renders the food (here animal

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[6]Other ubiquitous environmental contaminants covered by FDA action levels are cadmium, crotolaria seeds, lead, mercury, nitrosodimethylamine, paralytic shellfish toxin, and polybrominated biphenyls (PBBs). *See*, Food Drug Cosm. L. Rep. (CCH) ¶ 50285.

feed) adulterated under the "may be injurious to health" standard of Section 402(a)(1) of the Act, a state agency could independently bring an action under its state food and drug statute.[7]

Feed manufacturers may be exposed to lawsuits by customers. Such a suit may be brought for breach of warranty since the product would be "illegal" if it contained any level of a contaminant. Alternatively, since a violation of a public health statute is negligence *per se* under many state laws and state court decisions,[8] the decision below may trigger court actions by farmers whose livestock or poultry develop health problems and who seek to blame the "illegal" feed without any scientific evidence demonstrating the contaminants actually harmed the animals.

Finally, AFIA is concerned that the Court of Appeals opinion will result in companies being forced to violate the law since it will be virtually impossible to obtain "pure" feed ingredients. AFIA's members are committed to producing safe and legal feed products. Any holding which questions the legality of this nation's entire food supply is suspect and, as will be shown below, is incorrect.

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[7]Most state food and drug laws parallel the federal Act, including the "may render injurious" prohibition of Section 402(a)(1). *See e.g.*, Cal. Health and Safety Code § 26520 (Deering 1984) and N.Y. Agric. and Mkt. Law § 200 (Consol. 1939).

[8]*See, Texsun Feed Yards, Inc. v. Ralston Purina Company*, 447 F.2d 660 (5th Cir. 1971); *Utah Cooperative Association v. Egbert-Haderlie Hog Farms*, 550 P.2d 196 (Utah 1976); *Kassab v. Central Soya*, 432 Pa. 217, 246 A.2d 848 (1968); *See also, Ezagui v. Dow Chemical Corp.*, 598 F.2d 721 (2nd Cir. 1979).

SUMMARY OF ARGUMENT

The Court of Appeals decision is wrong as a matter of statutory construction. Under Section 402(a)(1) of the Act, 21 U.S.C. § 342(a)(1), a food, including animal feed, is adulterated *only* if the quantity of the contaminant is present in an amount so that food containing the contaminant "may be injurious to health." By holding that the mere presence of any level of an unavoidable environmental contaminant renders the food adulterated, the Court of Appeals totally misconstrued this provision of the Act and, at the same time, overturned this Court's opinion in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914). From this incorrect premise concerning Section 402(a)(1) of the Act, the Court of Appeals erred in concluding that the Section 406 requirement for an official and formal tolerance applied to this case. As this Court recognized in *Flemming v. Florida Citrus Exchange*, 358 U.S. 156 (1958), Section 402(a)(1) of the Act is the general test of adulteration and Section 406 comes into play *only* to sanction that which is prohibited by Section 402(a)(1). Since Section 402(a)(1), not Section 406, applies to the present case, the Court of Appeals incorrectly ruled that formal tolerances were required.

ARGUMENT

I. THE MERE PRESENCE OF AN UNAVOIDABLE ENVIRONMENTAL CONTAMINANT IN FOOD DOES NOT RENDER THE FOOD ADULTERATED UNDER SECTION 402(a)(1) OF THE ACT AS A MATTER OF LAW

In its opinion, the court below held that FDA must establish a tolerance in order for a food containing

unavoidable added poisonous or deleterious substances to be considered "unadulterated."[9] Since a tolerance is only required to sanction what would otherwise amount to adulteration, *Flemming v. Florida Citrus Exchange*, 358 U.S. 156 (1958), the court must have found that the very presence of any level of a poisonous or deleterious substance renders the product adulterated. This finding ignores the plain meaning of Section 402(a)(1), its legislative history, and this Court's opinion in *United States v. Lexington Mill and Elevator Co.*, 232 U.S. 399 (1914).

A. The Plain Language Of Section 402(a)(1) Requires A Showing That The Quantity Of Contaminant Poses A Health Risk

Section 402(a)(1) provides, in relevant part, that "a food shall be deemed adulterated. . .if it bears or contains any poisonous or deleterious substance *which may render it injurious to health. . . .*" (emphasis added). The Court of Appeals decision reads the statute without that final and qualifying phrase which requires FDA and the courts to look at the effect of the contaminant on health. Obviously, had Congress intended that the mere presence of an unavoidable poisonous or deleterious substance in food is sufficient for a finding of adulteration, it would not have added the qualifying final phrase.[10] Accordingly, under the

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[9] *Pet. App.* at 15a.

[10] For example, in the case of *avoidable* and unnecessary poisonous or deleterious substances, Congress in Section 406 of the Act declared foods containing such contaminants to be unsafe without qualification and adulterated under Section 402(a)(2)(A). Thus, there is no added requirement of showing a risk to health from the food containing the avoidable environmental contaminant. In the case before this Court, it is undisputed that aflatoxin is *unavoidable*. *Pet. App.* at 4a.

plain language of the statute, the question to be addressed and resolved is not so simple as whether the food contains any level of an environmental contaminant, but rather, the more difficult question of whether the *quantity* of the contaminant poses a risk to health.

B. The Legislative History Of Section 402(a)(1) Shows That Congress Did Not Intend To Establish A Per Se Rule

The "may render injurious to health" standard first appeared in Section 7 of the Pure Food and Drugs Act of 1906. (34 Stat. 769). When the statute was revised in 1938, Congress retained this standard mainly because this Court had reasonably construed this provision in the *Lexington Mill* case. *Flemming v. Florida Citrus Exchange*, 358 U.S. at 161.

The legislative history accompanying the 1906 Act makes clear Congress did not intend to render adulterated all foods containing any level of contamination. Mr. Heyburn, chairman of the committee reporting the bill on the Senate floor, stated:

> "As to the use of the term 'poisonous,' let me state that everything which contains poison is not poison. It depends on the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends on the combination, the chemical relation which it bears to the body in which it exists as to whether or not it is dangerous to take into the human system. . . ."

Lexington Mill, 232 U.S. at 412. Thus, it was never the Congressional intent to declare any food to be

adulterated for bearing unavoidable "poisons" in trace and innocuous amounts.

C. This Court Has Held That The Mere Presence Of A Poisonous Or Deleterious Substance, Without More, Does Not Constitute Adulteration Proscribed By The Act

In 1914, this Court was presented with the issue of whether Section 7 of the 1906 Act condemned the presence of any amount of a contaminant in food. There, a flour mill had treated its flour with a bleaching agent, nitrous oxide, which was considered a poisonous or deleterious substance. The federal government instituted legal proceedings to seize and condemn the flour bearing the nitrous oxide under Section 7 of the 1906 Act. In its instructions to the jury, the trial court "regarded the addition to the flour of any poisonous ingredient as an offense within the statute, no matter how small the quantity and whether the flour might or might not injure the health of the consumer." *Lexington Mill*, 232 U.S. at 408.

This Court reversed, holding the trial court erred in its jury instructions. According to this Court:

> "The act has placed upon the government the burden of establishing, in order to secure a verdict of condemnation under this statute, that the added poisonous or deleterious substances must be such as may render such article injurious to health. . . . If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act."

Id. at 411.

This holding has been effectively reversed by the court below. If the decision is affirmed by this Court, the government need not show any risk to the public health from food containing innocuous levels of environmental contaminants; rather, it need merely show that the product contains a poisonous or deleterious substance. This is in direct contradiction to the plain language in Section 402(a)(1), its legislative history, and this Court's prior opinion in *Lexington Mill.*

II. SECTION 406 DOES NOT MANDATE FDA ESTABLISH A TOLERANCE FOR ALL POISONOUS OR DELETERIOUS SUBSTANCES

After erroneously concluding the mere presence of a poisonous substance, at even innocuous levels, renders a food adulterated, the court below proceeded to apply the Section 406 requirement of formal tolerances. Yet, as will be shown below, Section 406 simply does not apply.

A. Section 406 Does Not Apply To The Factual Situation Here

As the language of Section 406 of the Act[11] demonstrates, the provision addresses only two discreet situations. First, the addition of any poisonous or deleterious substance which is *unnecessary* and *avoidable* renders the product adulterated under Section 402(a)(2)(A). Second, if a formal tolerance for a *necessary* or *unavoidable* contaminant is established, a product containing levels of the contaminant in excess of the tolerance is also adulterated under Section 402(a)(2)(A). Section 406 does not cover poisonous or

[11]*See supra* note 2, p. 5 for the language of Section 406.

deleterious substances which are necessary or unavoidable and for which no tolerance is established. Indeed, since Section 406 does not apply to necessary or unavoidable substances, a food containing such a substance is not adulterated under Section 402(a)(2)(A); rather, Section 402(a)(1) applies together with its "may render injurious to health" standard.

In the instant proceeding, there is no dispute that aflatoxin is neither necessary nor avoidable. It is derived from an unavoidable field mold that produces a toxin on raw agricultural commodities. It is unnecessary but cannot be prevented or eliminated through good manufacturing practices. Accordingly, it does not fall within the first clause of Section 406. Likewise, it is agreed that *no* tolerance has been established for aflatoxin on corn and the second situation covered by Section 406 is not present here. In sum, the nature of aflatoxin contamination and its lack of utility in food products does not fall within the plain language of Section 406.

B. The Purpose Of Section 406 Tolerances Is To Sanction What Otherwise Would Be Adulteration Under Section 402(a)(1)

In the decision below, the Court of Appeals placed undue importance on the word "shall" in Section 406.[12] The court below indicated that this word imposed an affirmative obligation on FDA to establish tolerances in all cases.[13] However, all other federal

[12]The relevant language of this provision reads:

> "The Secretary shall promulgate regulations. . .to such extent as he finds necessary for the protection of the public health. . . ."

[13]*Pet. App.* at 6a.

Courts of Appeal which have considered this question have interpreted Section 406 differently: that no such affirmative obligation exists. *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir. 1980); *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979); *cf. Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 236 F.2d 866 (2nd Cir. 1956).[14]

If Section 406 does not mandate tolerances in all cases, the question becomes when such a requirement comes into play. This question has been answered by this Court in *Flemming v. Florida Citrus Exchange*, 358 U.S. at 166. There, this Court stated:

> "The existence of a tolerance is specifically stated in 406(a) [currently 406] *only* to give sanction to what would otherwise amount to adulteration within the terms of 402(a)(1)."

Id. (Emphasis added). Accordingly, if the level of contamination does not violate the "may render injurious to health" standard of Section 402(a)(1), no tolerance is authorized or required.

In determining whether Section 402(a)(1) is violated, it is insufficient to show the mere presence of an environmental contaminant. Instead, FDA must

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[14]The court below attempted to distinguish these cases as being enforcement cases having nothing to do with whether FDA could affirmatively authorize a shipment of a product bearing innocuous levels of a contaminant. The court misconstrued the relevant import of the cases. These cases properly interpreted the word "shall" in Section 406 to mean there is no affirmative duty on the FDA to establish tolerances for any and all levels of a contaminant in food. As discussed below, the duty is triggered only in one specific instance.

show the contaminant is present at a level in a food which may render the food injurious to health. The determination as to that level of contamination which meets the Section 402(a)(1) standard necessarily implicates complex chemical, biological, and toxicological considerations. In such cases, it is appropriate for a court to give great deference to the agency with expertise in the area. *See, e.g., United States v. Boston Farm Center*, 590 F.2d 149 (5th Cir. 1979), *cf. Heckler v. Chaney*, 105 S. Ct. 1648 (1985); *United States v. Rutherford*, 442 U.S. 544 (1979).

FDA has used its expertise to make such determinations for various contaminants. The determinations as to those levels of unavoidable environmental contaminants which would be tantamount to a Section 402(a)(1) violation are called "action levels." FDA uses action levels as an enforcement guide specifying that level of contamination which the agency believes is necessary to establish a violation of Section 402(a)(1) of the Act in court. Action levels constitute the maximum safe and legal limit of an unavoidable or necessary contaminant. Thus, food bearing an amount of contaminants below FDA's action levels does not fall within the ambit of Section 406 since the food would not meet the "may render injurious standard" and does not violate Section 402(a)(1).

C. Since FDA Found No 402(a)(1) Violation, The Agency, By Modifying The Action Level, Acted In Compliance With The Federal Food, Drug, And Cosmetic Act

As discussed above, state governments petitioned FDA to approve the controlled and limited distribution of corn containing less than 100 ppb aflatoxin. The states submitted that the scientific evidence and the regulatory plan clearly established that such corn

could be safely used in animal feed for mature non-lactating livestock and poultry. Upon its review of the scientific evidence and the plan, FDA agreed that such use posed no risk to animals or to humans who consumed the edible tissue from the animals.

It is important to emphasize that FDA did not change its previous 20 ppb action level for the unrestricted use of corn. This general prohibition was expressly maintained in full force and effect by the agency. What FDA was requested to do was rule on the safety of a *specific* use under a *specific* regulatory program.

By making this determination, FDA found that this limited use did not violate § 402(a)(1) of the Act. Absent a § 402(a)(1) violation FDA was not mandated to establish a 406 tolerance and, in short, FDA acted in full compliance with the Federal Food, Drug, and Cosmetic Act.

CONCLUSION

For the foregoing reasons, *Amicus*, American Feed Industry Association, respectfully requests this Honorable Court to reverse the decision of the Court of Appeals.

Respectfully submitted,

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No. 85-664

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF NATIONAL PEANUT COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Food and Drug Administration is required to regulate unavoidable added poisonous or deleterious substances in food by adopting tolerances through formal rulemaking pursuant to § 402(a)(2)(A) (21 U.S.C. § 342(a)(2)(A)), rather than by adopting informal action levels administered by case-by-case adjudication pursuant to § 402(a)(1) (21 U.S.C. § 342(a)(1)).

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Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF NATIONAL PEANUT COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

The National Peanut Council, Inc. ("NPC"), by its attorneys, files this brief as *amicus curiae* in support of the Petitioner, Frank Young, Commissioner of Food and Drugs, and respectfully urges the Court to reverse the judgment entered by the United States Court of Appeals for the District of Columbia Circuit in the above-captioned case. Consent to file this brief has been obtained from counsel for all parties and has been filed with the Clerk of this Court.

INTEREST OF *AMICUS CURIAE*

The National Peanut Council, Inc. ("NPC") is a non-profit Georgia corporation, chartered in 1940, which rep-

resents and serves individuals, companies, corporations, and associations engaged in, or providing goods or services to, the production, processing, marketing, or manufacturing of peanuts and peanut products. NPC members include peanut growers and affiliated associations, shellers, custom processors, brokers, manufacturers, and international and allied entities.

The subject matter of the instant case—whether the Food and Drug Administration ("FDA") is required to regulate unavoidable added poisonous or deleterious substances in food by means of tolerances promulgated through formal rulemaking, rather than by informal action levels resulting in case-by-case adjudication—is of great concern to NPC, since the specific substances at issue here, aflatoxins, are chemical byproducts of molds that grow on numerous agricultural commodities. Furthermore, NPC and its members would be adversely affected by an interpretation of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§ 301-392 ("FDCA"), that renders adulterated all foods which contain detectable amounts of any unavoidable added poisonous or deleterious substance, unless and until a tolerance for each substance and food has been established and promulgated by the FDA.

The interest of NPC is predicated upon the substantial and far-reaching consequences of the result of the instant case. The concern of the *amicus curiae* is that the Court, in formulating the principles to govern the interpretation of key sections of the FDCA involved in the present case, should have the benefit of NPC's views, which may not otherwise be presented in the arguments of the parties, in order to be aware of the broad ramifications of its decision herein.

STATEMENT OF THE CASE

This case presents a challenge to the FDA's method of regulating the interstate commerce of foods which evidence any added poisonous or deleterious substance that is required in the production of food or that cannot be avoided by good manufacturing practices. Since the enactment of the FDCA in 1938, FDA has regulated substances like aflatoxins principally by issuing action levels, which announce the level of the particular substance that FDA regards as resulting in adulteration under § 402(a)(1).[1]

Respondents brought this suit to challenge FDA's implementation of the adulteration provisions of the FDCA to aflatoxins in corn products. Respondents contended that: (1) FDA should be compelled to adopt a formal aflatoxin tolerance pursuant to § 406,[2] as opposed to an informally implemented action level; (2) the action level, in the alternative, should be made subject to notice-and-comment rulemaking; and (3) certain exemptions to the action level were contrary to law. The United States District Court for the District of Columbia noted that the FDA had promulgated a final rule governing the use of action levels and formal tolerances,[3] that the language of § 406 had been interpreted by FDA "to mean that, in its discretion, it may decide that a tolerance is not necessary to protect the public health and therefore can decline to establish one,"[4] and that an agency's interpretation of its statute is entitled to substantial deference. Therefore, the court found that FDA's construction of § 406 was reasonable and that § 406 "confers discretionary, not mandatory, authority on the agency to

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[1] 21 U.S.C. § 342(a)(1).

[2] 21 U.S.C. § 346.

[3] 42 Fed. Reg. 52814 (September 30, 1977), codified in 21 C.F.R. § 109.6 (food for human consumption) and § 509.6 (animal feed).

[4] Pet. App. 31a.

establish tolerances." Pet. App. 31a-32a (footnote omitted). The court granted FDA's motion for summary judgment on all three issues, concluded that "action levels" were general statements of policy not requiring notice-and-comment rulemaking, and further stated that the exemptions granted were within the agency's discretion. Pet. App. 32a-34a.

The United States Court of Appeals for the District of Columbia Circuit reversed and held that "the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated."[5] The sole justification for the court's holding was its interpretation of the language of § 406 that "the Secretary shall promulgate regulations limiting the quantity [of unavoidable or required added poisonous or deleterious substances in food] to such extent as he finds necessary for the protection of public health."[6] The court interpreted the clause "to such extent as he finds necessary for the protection of public health" as not modifying "the pivotal word 'shall',"[7] and inferred that the "Secretary must promulgate regulations embodying tolerances."[8] The court reiterated its holding by stating that, "(s)ince the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." Pet. App. 7a.

In interpreting the FDCA to require tolerances, the court rejected FDA's longstanding interpretation of the FDCA,[9] characterized the legislative history supporting

[5] Pet. App. 15a.

[6] 21 U.S.C. § 346.

[7] Pet. App. 7a.

[8] Pet. App. 7a.

[9] Pet. App. 6a.

FDA's interpretation as inconclusive,[10] dismissed all relevant cases on the ground that they did not address the issue *sub judice*,[11] and cited no judicial, legislative, or administrative authority that has ever interpreted the FDCA in the manner adopted by the court.

SUMMARY OF ARGUMENT

In support of Petitioner, NPC respectfully urges that the Court reverse the judgment entered by the United States Court of Appeals for the District of Columbia Circuit for the following reasons:

(1) The District of Columbia Circuit's interpretation is not supported by the language or plain meaning of the FDCA,

(2) The District of Columbia Circuit's interpretation is not supported by the legislative history of the FDCA,

(3) The District of Columbia Circuit's interpretation is in conflict with FDA's longstanding administrative interpretation, which was acknowledged and unaltered by Congress and is entitled to substantial deference,

(4) The District of Columbia Circuit's interpretation violates a sound principle of statutory construction, that a statute be construed so as to give effect to all of its provisions, and has the effect of rendering the key adulteration standard of § 402(a)(1) totally inoperative, and

(5) The District of Columbia Circuit's interpretation is not supported by prior case law.

Therefore, NPC respectfully suggests that Congress has conferred upon FDA the customary agency discretion to determine whether, *i.e.*, to what extent the protection of public health requires, a formal tolerance be promulgated in any given circumstance.

[10] Pet. App. 9a-11a.

[11] Pet. App. 13a, 15a.

ARGUMENT

I. THE COURT OF APPEALS' INTERPRETATION OF THE FDCA IS NOT SUPPORTED BY THE LANGUAGE OR PLAIN MEANING OF THE FDCA

The FDCA, at §§ 402(a) and 406, delegated authority to the FDA to regulate added poisonous or deleterious substances in food. It is not disputed that aflatoxin is an unavoidable added poisonous or deleterious substance; however, the FDCA does not define any aflatoxin-tainted corn to be adulterated absent (1) FDA's determination that the presence of aflatoxin in corn may render the food injurious to health, or (2) FDA's discretionary promulgation of a formal tolerance. The analysis presented below clearly demonstrates that the interpretation of the District of Columbia Circuit is not supported by the language or plain meaning of §§ 402(a) and 406.

The pertinent part of § 402(a) provides that:

> A food shall be deemed to be adulterated—
>
> (a) *Poisonous, insanitary, or deleterious ingredients.* (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406 [21 U.S.C. § 346], or (B) if it is a raw agricultural commodity and it bears or contain a pesticide chemical which is unsafe within the meaning of section 408(a) [21 U.S.C. § 346a(a)], or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409 [21 U.S.C. § 348].

Under the first clause of § 402(a)(1), any food containing any added poisonous or deleterious substance is deemed adulterated, only if the added poisonous or deleterious substance may render the food injurious to health. This Court held, in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 410 (1914), that, under the plain meaning of subdivision five of § 7 of the Food and Drugs Act of 1906,[12] the mere presence of an added poisonous or deleterious substance does not render a food adulterated.[13] The added substance must be shown to be present in such amounts that might render the food injurious to health.

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[12] Section 7 of the Food and Drugs Act of 1906, 34 Stat. 769, provides in pertinent part:

> Sec. 7 That for the purposes of this act an article shall be deemed to be adulterated: . . . In the case of food:
>
> . . .
>
> Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health.

[13] (W)e find that the fifth subdivision of § 7 provides that food shall be deemed to be adulterated: "If it contain(s) any added poisonous or other added deleterious ingredient *which may render such article injurious to health.*" The instruction of the trial court permitted this statute to be read without the final and qualifying words, concerning the effect of the article upon health. If Congress had so intended the provision would have stopped with the condemnation of food which contained any added poisonous or other added deleterious ingredient. In other words, the first and familiar consideration is that, if Congress had intended to enact the statute in that form, it would have done so by choice of apt words to express that intent. It did not do so, but only condemned food containing an added poisonous or other added deleterious ingredient when such addition might render the article of food injurious to health.

United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 410-411 (1914) (emphasis in original).

In *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958), the Court, construing the Federal Food, Drug, and Cosmetic Act of 1938, held that the rule of *Lexington Mill* continued to apply under the first clause of § 402 (a) (1).[14]

Since the FDA has not determined that the mere presence of any amount of aflatoxin in food may render such food injurious to health, foods containing aflatoxin are not deemed to be adulterated under the first clause of § 402(a)(1). We turn to the adulteration standard set forth in § 406, which is referred to by § 402(a)(2)(A), under which a food is deemed adulterated if it contains "any added poisonous or deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406." [15]

The initial part of § 406 provides that:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [21 U.S.C. § 342(a)(2)(A)]; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [21 U.S.C. § 342(a)(2)(A)].

[14] *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 160-1 (1958); *United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151, 1155-6 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157, 159 (5th Cir. 1980). *See also, Certified Color Industry Committee v. Secretary of Health, Education & Welfare*, 236 F.2d 366, 869 (2d Cir. 1956); H.R. Rep. No. 2356, 82d Cong., 2d Sess. 21-22 (June 30, 1952).

[15] Other more specific statutory standards are prescribed in §§ 402(a)(2)(B) and 408 for registered pesticides in foods; in §§ 402(a)(2)(C) and 409 for food additives in foods; in §§ 402(c) and 706 for color additives; and in §§ 402(a)(2)(D) and 512 for new animal drugs. 21 U.S.C. §§ 342, 346a, 348, 376, and 360b.

Thus, an added poisonous or deleterious substance shall be deemed to be "unsafe" for purposes of § 402(a)(2)(A) in two circumstances: (1) under the first clause of § 406, any amount of such substance is unsafe if it is not required in production or is not unavoidable; and (2) under the third clause of § 406, if a tolerance has been adopted for an added poisonous or deleterious substance that is required in production or is unavoidable, the substance is deemed unsafe if it exceeds the quantity prescribed by a tolerance. The remainder of § 406 provides that:

> While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a) [21 U.S.C. § 342(a)(1)]. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

The language of § 406 prescribes no safety standard for added poisonous or deleterious substances which are required or unavoidable and for which a tolerance has not been promulgated. Neither criteria of § 406 for added poisonous or deleterious substances to be deemed "unsafe" applies to an added poisonous or deleterious substance which is required in production or is unavoidable and for which no tolerance has been prescribed. This

is not an omission by Congress in drafting the FDCA. The adulteration standard set forth in § 402(a)(1) remains applicable for added poisonous or deleterious substances and FDA promulgates and enforces action levels limiting the presence of such substances under that section.

The language and plain meaning of § 406 does not *require* FDA to establish formal tolerances. The second clause of § 406—"but when such [added poisonous or deleterious] substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such as he finds necessary for the protection of public health,"—is not a directive that compels FDA to promulgate formal tolerances. The Court of Appeals held that the phrase "to such extent as he finds necessary for the protection of the public health" does not modify the pivotal word "shall," and that the overall structure of the statutory scheme supports its conclusion that the phrase explains the standard that the Secretary is to employ in setting formal tolerance. Pet. App. 7a. The Court of Appeals' interpretation is in error in both instances.

The plain meaning of the language of § 406 is to confer authority (*i.e.*, permission) upon the Secretary to promulgate tolerances. The critical phrase noted above modifies the pivotal word "shall" and expresses the Congressional intent that tolerances may be utilized, in the Secretary's discretion, to effect the purpose of the FDCA—to protect public health.[16] The last sentence of § 406 explains the quantitative standard the Secretary is required to employ in setting the tolerance, the critical phrase performs no such office.

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[16] *United States v. Kordel*, 164 F.2d 913 (7th Cir. 1947), *aff'd*, 335 U.S. 345 (1948); *United States v. Two Bags, Poppy Seeds*, 147 F.2d 123 (6th Cir. 1945); *Barnes v. United States*, 142 F.2d 648 (9th Cir. 1944).

The analysis offered by the Court in *Lexington Mill*,[17] supports Petitioner's interpretation and plain meaning analysis. If Congress had so intended that § 406 require FDA to establish tolerances, the language of the second clause of § 406 would have ended with the language—"the Secretary shall promulgate regulations limiting the quantity therein or thereon." Congress did not do so, but only directed the Secretary to establish tolerances "to such extent as he finds necessary for the protection of public health." Furthermore, it must be noted that Congress, in including the last phrase of the second clause of § 406, added a phrase that expressed the general purpose of the entire FDCA.[18] This express redundancy is entitled to even greater deference to its modifying position and interpretation.

II. THE COURT OF APPEALS' INTERPRETATION IS NOT SUPPORTED BY THE LEGISLATIVE HISTORY OF THE FDCA

The legislative history of the FDCA does not support the Court of Appeals' interpretation that FDA is required to promulgate tolerance levels for required or unavoidable added poisonous or deleterious substances. The report accompanying S. 5, a bill to amend the FDCA, as reported to the Senate,[19] described section 304(a), enacted as § 406(a), to "authorize the establishment of tolerances for the protection public health in those instances where the addition of the poison is required or cannot be avoided," [20] and "delegate authority for the

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[17] *See* n.13.

[18] *United States v. Kordel*, 164 F.2d 913 (7th Cir. 1947), *aff'd*, 335 U.S. 345 (1948); *United States v. Lord-Mott Co.*, 57 F. Supp. 128 (D. Md. 1944).

[19] S. Rep. No. 686, 74th Cong., 1st Sess. (May 13, 1935).

[20] *Id.* at 3.

establishment of tolerances so limiting the amount of poisons as to protect the public health." [21]

On August 21, 1937, a subcommittee of the Committee on Interstate and Foreign Commerce of the House of Representatives published the text of the food, drug, and cosmetic bill, known as Committee Print No. 3, which was a revised substitute for S. 5 and incorporated H.R. 300, introduced by Mr. Chapman of Kentucky. The subcommittee offered no reason for the insertion of the word "shall" in § 406(a).[22]

Section 406(a) was construed and compared to the law in existence in 1938 as follows:

> Section 406, in subsection (a), provides for a fairer and more effective control of the addition of poisons to food than does the present law. This subsection first prohibits the unnecessary addition of poisons. *Where such additions are necessary, the establishment of tolerances is authorized, based upon the practical necessities for the use of poisonous substances.* It is well recognized that an adequate fruit and vegetable supply could not be brought to maturity without the use of toxic insecticides and fungicides. But the situation is made extremely complex by the number of poisonous substances used for different crops in different localities, and by contaminations which unavoidably occur in many manufacturing processes. The purpose of the subsection is to insure that the total amount of poisons the consumer receives will not be sufficient to jeopardize health. The needs of each branch of the food-producing industry can be met and the public health can be adequately protected.

[21] *Id.* at 5. S. 5, introduced by Senator Copeland of New York, passed the Senate on March 3, 1937.

[22] *See House Committee on Interstate and Foreign Commerce*, 75th Cong., 1st Sess., Committee Print No. 3 (August 19, 1937), *reprinted in* 81 Cong. Rec. (Appendix) 2341, 2344 (August 21, 1937).

H.R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (April 14, 1938) (emphasis added).

Prior to the 1954 pesticide amendments to the FDCA, the Select Committee to Investigate the Use of Chemicals in Food Products issued a report, entitled "Food." [23] After referring to § 402(a)(2) and citing § 406 in full, the report stated:

> *The primary purpose of section 406 was to provide a means by which maximum residue tolerances on food could be established for needed pesticides so as to protect the public health.* The Food and Drug Administration has completed hearings to establish tolerances on a large number of pesticides, and regulations are now being formulated. But the setting of tolerances does not give the Food and Drug Administration any advance control over the use of pesticides. Unless the manufacturer conducts adequate chronic toxicity tests for a new pesticide, the Government is powerless to afford the consumer any protection until it completes its own toxicity tests and conducts a formal public hearing for the purpose of issuing tolerance regulations. Both procedures consume more time than is consistent with efficient protection of the public health.

H.R. Rep. No. 2356, 82d Cong., 2d Sess. 22 (June 30, 1952) (emphasis added).

On July 14, 1953, the Subcommittee No. 2 of the Interstate and Foreign Commerce Committee held hearings on H.R 4277 of the 83d Congress, 1st Session, a pesticide amendment to the FDCA. The purpose of H.R. 4277 was to protect citizens from harmful chemical additives in pesticides by amending § 402(a)(2) to exclude pesticides from the language of § 406 and subject pesticides, under a final clause in § 402(a)(2), to a proposed new section, § 407 (subsequently enacted as § 408, 21 U.S.C. § 346a). As Congress desired that chemical additives in pesticides

[23] H.R. Rep. No. 2356, 82d Cong., 2d Sess. (June 30, 1952).

not be utilized without a tolerance having been promulgated, § 407 provided, in pertinent part, that:

> Any poisonous or deleterious pesticide added to food shall be deemed unsafe . . . [under § 402(a)(2)] unless (1) the quantity thereof does not exceed the limits of a tolerance prescribed by the Administrator under paragraph (b) of this section; or (2) the pesticide has been exempted from the requirement of a tolerance by the Administrator under paragraph (c) of this section.

§ 407(a), H.R. 4277, 83d Cong., 1st Sess.

Congress proposed and subsequently adopted a modified version of this language [24] to compel the Administrator to issue a pesticide tolerance or exempt a pesticide from the tolerance requirement, since Congress knew that the Department of Agriculture had held three years of hearings and expended some $500,000 in experiments and had not issued any tolerances for pesticides in foods under proceedings authorized by §§ 406 and 701(e) of the FDCA.[25]

In hearings before the Committee on Interstate and Foreign Commerce on H.R. 7125, 83d Cong., 2d Sess. (March 8, 1954),[26] Mr. Hinsaw introduced Mr. H. Thomas Austern, General Counsel of the National Canners Association, and placed Mr. Austern's letter, dated February 8, 1954, in the record. Speaking to the effect of H.R. 7125, a bill to amend the FDCA with respect to

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[24] *See* § 408(a), 21 U.S.C. § 346a(a).

[25] *See Hearings Before the Subcommittee No. 2 of the Interstate and Foreign Commerce Committee*, 83d Cong., 1st Sess. 118-121 (July 14, 1953) (Testimony of Mr. Crawford concerning H.R. 4277).

[26] H.R. 7125, similar in purpose and design to H.R. 4277 introduced on March 26, 1953, was introduced following conferences between authors of H.R. 4277, government officials, and farm and industry groups. *See* H.R. Rep. 1385, 83d Cong., 2d Sess. 4-5 (March 23, 1954).

residues of pesticide chemicals in or on raw agricultural commodities, Mr. Austern's letter stated:

> The association endorses this bill as introduced on January 11. This proposed legislation will, if passed, amend the Federal Food, Drug, and Cosmetic Act by providing a new procedure for the establishment of tolerances for residues of pesticide chemicals in or on raw agricultural commodities only. It is the understanding of the National Canners Association that after passage of this bill processed food will be in exactly the same position as before in that tolerances for pesticide residues with respect to processed food *may* be established under section 406 of the act; that *in the event* the Secretary acts to establish a tolerance for residues on processed foods under section 406 actions for adulteration will be taken under section 402(a)(2), but if the Secretary has not acted under section 406 any action for adulteration because of excessive pesticide residue in the processed food will still be taken under section 402(a)(1). This understanding of the canning industry is, we are advised, shared by Dr. Miller, by the FDA, and by all others interested in the legislation. The endorsement by the National Canners Association of H.R. 7125 on behalf of the canning industry is predicated on this understanding and the hope that your committee report will make it explicitly clear that the adulteration of processed foods will be dealt with exactly as before this amendment of the act.

Hearings Before the Committee on Interstate and Foreign Commerce on H.R. 7125, 83d Cong., 2d Sess. 31 (March 8, 1954).

The report concerning H.R. 7125 [27] demonstrates that Congress recognized the Secretary's discretion to promulgate tolerances and problems of issuing tolerances under § 406:

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[27] H.R. Rep. No. 1385, 83d Cong., 2d Sess. (March 23, 1954).

Existing law.

Under existing law, added poisonous and deleterious substances—and most pesticide chemicals fall in this class—must be kept out of foods unless they are required in production or cannot be avoided by good manufacturing practice. When such a substance is required in production—as many pesticide chemicals are required in growing agricultural crops—a tolerance *may* be established by the Secretary of Health, Education, and Welfare, but only after a formal public hearing. (The maximum amount of residue that may lawfully remain in or on the food is commonly referred to as a tolerance.) Detailed findings of fact and conclusions must be made by the Secretary as to the required use of the pesticide and the residue levels that may safely be tolerated.

Need for more legislation.

Regulations limiting the amount of pesticidal residue which may remain in or on food have been issued under the present law in only one instance, although the law authorizing such regulations has been in effect for over 15 years. During all that time control has been exercised through *unofficial and informal tolerances* [*i.e.*, action levels]. In 1950, lengthy public hearings were held for the purpose of establishing official tolerances (the maximum amount of poisonous of deleterious residue which may legally remain in or on food) for fresh fruits and vegetables. These hearings, at a cost of nearly a half-million dollars to Government, to industry, to agricultural organizations, and to the various land-grant colleges, produced a very large volume of evidence that had not theretofore been gathered together, but the record is still under consideration by the Government and the necessary tolerances have not yet been issued. This has been responsible for uncertainty under the law. It has handicapped the Government in enforcing the law, the grower in complying with the law, and the pesticide manufacturer and Federal and State agencies in discharging their responsibility for advising

and making recommendations to the grower with respect to the use of pesticide chemicals. This, together with the introduction of a large number of new pesticide chemicals, some of which are known to be toxic, has been responsible for concern that existing law is inadequate to protect the public health.

It has been generally recognized that a primary reason why tolerances have not been established to control agricultural usage of pesticide chemicals as intended by Congress has been the cumbersome, time-consuming, and impracticable procedure prescribed by existing law.

H.R. Rep. No. 1385, 83d Cong., 2d Sess. 2-3 (March 23, 1954) (emphasis added). Therefore, pertinent language of H.R. 7125 directed the Secretary of Health, Education, and Welfare to issue tolerances or exemptions from the tolerance requirements of § 408 within one hundred and eighty (180) days of the date a petition is filed under § 408(d) and specifically provided that a residue of a poisonous or deleterious pesticide chemical will be deemed unsafe under § 402(a)(2) if no tolerance or exemption has been established for it.[28]

Thus, Congress explicitly mandated tolerances or exceptions from tolerance for poisonous or deleterious pesticide chemical residues and, with knowledge that tolerances were not being established by the Secretary, repeatedly failed to amend § 406 to establish a similar mandate for unavoidable added poisonous or deleterious substances. The extended legislative history of the FDCA does not support the Court of Appeals' interpretation that § 406 requires the promulgation of tolerances or that unavoidable added poisonous or deleterious substances will be deemed adulterated in the absence of tolerances.

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[28] § 408(a), H.R. Rep. No. 2385, 83d Cong., 2d Sess. 7-8 (March 29, 1954); S. Rep. 1635, 83d Cong., 2d Sess. 4-7 (June 25, 1954).

III. FDA'S LONGSTANDING ADMINISTRATIVE INTERPRETATION OF THE FDCA, WHICH WAS RECOGNIZED AND UNALTERED BY CONGRESS IN 1954, IS IN CONFLICT WITH THE COURT OF APPEALS' INTERPRETATION

As cited above, Congress noted FDA's interpretation of §§ 402 and 406 in its 1954 legislative history and repeatedly chose not to amend §§ 402 and 406 to alter FDA's interpretation. Thus, FDA rightfully continues to adhere to its interpretation of §§ 402 and 406, as demonstrated in its 1974 proposal relating to the adoption of action levels[29] and its preamble to the promulgation of final regulations,[30] incorporated as Part 109—Unavoidable Contaminants in Food for Human Consumption and Food —Packaging Material, Chapter I of Title 21, of the Code of Federal Regulations, which stated:

> In establishing an action level, the Commissioner must consider the extent to which the contaminant is unavoidable, which is the policy embodied in section 406 of the act.
>
> . . .
>
> In setting a tolerance or action level the Commissioner considers the other ways in which the consumer may be affected by the same substance or other substances.

39 Fed. Reg. 42738 (December 6, 1974). FDA has repeatedly expressed its interpretaiton of §§ 402 and 406 as *permitting* the establishment of tolerances:

> "Section 406 of the act *permits* the establishment of tolerances for added poisonous or deleterious substances in food . . ."

39 Fed. Reg. 42743 (December 6, 1974),

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[29] 39 Fed. Reg. 42743 (December 6, 1974).

[30] 42 Fed. Reg. 52814 (September 30, 1974).

> Section 406 was included in the 1938 act to *permit* the establishment of tolerances for added poisonous or deleterious substances which are required in the production of food or otherwise cannot be avoided by good manufacturing practice. A limitation may be placed upon such substances to the extent necessary for the protection of the public health. Although formal tolerances under section 406 have not been used by the Food and Drug Administration, except for the tolerance for PCB's published in the *Federal Register* of July 6, 1973 (38 FR 18096), informal action levels have frequently been utilized to implement this provision of the law and a number of those action levels exist today.

39 Fed. Reg. 42744 (December 6, 1974), and

> When a tolerance is established under the provisions of section 406, the act requires it to be set at the level necessary for the protection of the public health taking into account the extent to which the substance cannot be avoided and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.
>
> At times it will not be appropriate to establish a formal tolerance. *The Commissioner is not required to establish a tolerance for every added poisonous or deleterious substance*, as is indicated by the language of section 406 of the act recognizing that an adulteration charge can be made under section 402(a)(1) of the act when no tolerance is in effect. Section 306 of the act has long been interpreted to permit the Food and Drug Administration to establish action levels in implementing the adulteration provisions of the act.

39 Fed. Reg. 42745 (December 6, 1974) (citations omitted, emphasis added).

Thus, for almost fifty years, FDA has adopted the interpretation that § 406 grants discretionary authority to establish tolerances, and during that time has promul-

gated few tolerance levels, but an enormous number of action levels. In the hearings addressing the 1954 amendments to the FDCA, Congress recognized FDA's interpretation of §§ 402 and 406 and allowed the language of those sections to remain unaltered with respect to required or unavoidable added poisonous or deleterious substances. A comparison of the language and structure of § 408(a)-(c)[31] of the 1954 amendments with § 406 clearly reveals that the intent of Congress was to mandate that tolerance levels or exemptions from a tolerance requirement be established for pesticide residues in foods.[32] The language and structure of the pesticide chemical amendments are a model of clarity and purpose. Section 402(a)(2) was amended to deem foods containing pesticide chemicals "adulterated," if such food contain added pesticide chemicals which are "unsafe" under § 408(a).[33] Section 408(a) then defined any added poisonous or deleterious pesticide chemical to be "unsafe" for purposes of § 402(a)(2)(B) *unless* (1) a tolerance had been established and the quantity of such pesticide chemical is below the tolerance level prescribed,[34] or (2) the pesticide chemical had been exempted from the tolerance requirement.[35]

Significantly, Congress failed to alter the language or structure of § 406 to parallel that of § 408 and, by its inaction, implicitly authorized and sanctioned the interpretation of § 406 that permits, but does not require, FDA to establish tolerance levels for unavoidable added poisonous or deleterious substances which are not pesticide chemicals.

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[31] 21 U.S.C. § 346a(a)-(c).

[32] § 408(a); 21 U.S.C. § 346a(a).

[33] § 402(a)(2)(B); 21 U.S.C. § 342(a)(2)(B).

[34] § 408(a)(1), 21 U.S.C. § 346a(a)(1).

[35] § 408(a)(2), 21 U.S.C. § 346a(a)(2).

IV. THE COURT OF APPEALS' INTERPRETATION VIOLATES THE PRINCIPLE OF STATUTORY CONSTRUCTION THAT A STATUTE WILL BE CONSTRUED SO AS TO GIVE EFFECT TO ALL OF ITS PROVISIONS

As a general principle of statutory construction, a statute will be construed so as to give effect to all of its provisions. *See, e.g., Dickerson v. New Banner Institute, Inc.*, 460 U.S. 103, 118 (1983). However, the District of Columbia Circuit's unprecedented interpretation of §§ 402 and 406 renders meaningless and superfluous the key adulteration provision of § 402(a)(1) that foods containing added substances be deemed adulterated if the substance may render the food injurious to health. Sections 402(a) and 406 regulate added poisonous or deleterious substances under three classifications: (1) substances which are not required or unavoidable, (2) substances which are required or unavoidable and for which a tolerance has been established, and (3) substances which are required or unavoidable and for which a tolerance has not been established. Substances within the first classification are absolutely banned by §§ 402(a)(2)(A) and 406, and thus the "may render" standard of § 402(a)(1) has no application to such substances. Likewise, § 402(a)(1) has no application to substances within the second classification, since §§ 402(a)(2)(A) and 406 explicitly displace § 402(a)(1) when a tolerance has been promulgated for required or unavoidable added poisonous or deleterious substances. Thus, § 402(a)(1) can only apply to the third classification—required or unavoidable added poisonous or deleterious substances for which no tolerance has been established. The Court of Appeals interprets § 406 as if it provides that any required or unavoidable added poisonous or deleterious substance is deemed unsafe, unless a tolerance has been established. If this were the case, then §§ 402(a)(2)(A) and 406 would govern the third classification of substances, and § 402(a)(1) would be rendered totally inoperative. This is contrary

to the intent of Congress and the sound principle of statutory construction noted above. The Court should strive to interpret these provisions consistently since §§ 402 (a)(1) and 402(a)(2)(A) were enacted together in 1938.

Thus, if unavoidable added poisonous or deleterious substances must be regulated by tolerances under § 406, no purpose or effect remains for the first clause of § 402(a)(1). The Court of Appeals' interpretation renders § 402(a)(1) inoperative and meaningless, clearly disregards the intent of Congress, violates a sound principle of statutory construction, and must be reversed.

V. CASE LAW DOES NOT SUPPORT THE COURT OF APPEALS' INTERPRETATION

Ample case law on the very issue before this Court supports Petitioner's position. In *United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980), Chief Judge Arnow noted that "Anderson also contended that FDA was required to establish a tolerance for mercury in swordfish under 21 U.S.C. § 346 (1975) [§ 406]. The court ruled prior to trial that this contention was without merit." 447 F. Supp. 1151, 1153, n.2. The court does not claim, as the District of Columbia Circuit implied, that defendant's contention was that FDA was required to establish tolerances under § 406 *before* taking enforcement action pursuant to the FDCA. In fact, the issue of whether FDA is required to establish tolerances arose from Anderson's complaint for declaratory and injunctive relief, not from the enforcement action asserted by the United States.[36]

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[36] The "two cases were consolidated and tried jointly because they shared fundamental questions of fact and law." 447 F. Supp. 1151, 1153.

In *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), an action to enjoin shipment of aflatoxin-tainted corn, the Fifth Circuit stated:

> The 20 ppb level proposed by the Government is the Food and Drug Administration's "action level" for aflatoxin in corn. An action level, to be defined properly, must be explained in the broader context of the FDA's general regulatory scheme. *In implementing the Act, the FDA either may adopt formal regulations, 21 U.S.C. § 346, or may litigate alleged violations on a case-by-case basis.* Although the Act makes illegal any amount of substance which "may render (food) injurious to health" 21 U.S.C. § 342(a)(1) the FDA is not required to seek to enjoin, prosecute or otherwise litigate "minor violations" of the Act. 21 U.S.C. § 336. To guide its prosecutorial discretion in the bringing of non-rule enforcements of the Act the FDA may establish certain inhouse guidelines called action levels. Since 1969 the action level for aflatoxin in corn has been 20 ppb. This means that since 1969 the FDA's internal policy has been to try to prevent the shipment of corn containing more than 20 ppb of aflatoxin, but not of corn containing 20 ppb or less.

Id. at 151 (emphasis added). The court held that, on the evidence presented, it was clearly erroneous to find that amounts of aflatoxin between 20 ppb and 100 ppb do not adulterate corn and enjoined shipment of corn containing more than 20 ppb of aflatoxin. Thus, the Court expressly sanctioned FDA's regulation of aflatoxin in corn by issuing action levels rather than tolerances. The Court of Appeals' characterization of *Anderson Seafoods* and *Boston Farm Center*, as involving only the ability of the United States to prohibit shipment of food without having first established a tolerance, is an inappropriate and unduly narrow view of the issues arising in these cases. The critical issue is the manner in which FDA must regulate food under the FDCA,

whether or not it permits shipment of such food. The Court of Appeals' attempt to distinguish the above cases, on the basis that they simply do not speak to the agency's refusal to establish a tolerance while permitting shipment, is absurd. The *Boston Farm Center* court expressly noted that "(t)o an extent the statutory scheme permits the FDA to adopt a relatively *ad hoc* case-by-case approach to regulating the poisons in our food," *id.* at 152-3, and it is common sense that, should FDA decide not to bring an enforcement action, FDA is permitting shipment.

While courts have expressed their belief in dicta that § 406 "apparently mandated that the FDA establish tolerances for added poisonous or deleterious substances which are required or unavoidable in the production of food," *United States v. General Foods Corp.*, 466 F. Supp. 740, 785 (N.D.N.Y. 1978), *aff'd*, 591 F.2d 1332 (2d Cir. 1978), such statements do not support the Court of Appeals' unprecedented interpretation, which reverses an FDA practice of almost fifty years' duration. Furthermore, the Court of Appeals cannot place reliance upon *United States v. Goodman*, 353 F. Supp. 250 (E.D. Wisc. 1972), *aff'd*, 486 F.2d 847 (7th Cir. 1973), *aff'd sub nom., United States v. Ewig Bros. Co., Inc.*, 420 U.S. 945 (1975), as the intent of Congress in the 1954 pesticide amendments to the FDCA, which culminated in the § 408 requirement that the FDA establish tolerances or grant exemptions from the tolerance requirement for pesticides, is not analogous to § 406's grant of authority to promulgate tolerances.

In *Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 236 F.2d 866 (2d Cir. 1956), the court stated that "(s)ection 406(a), 21 U.S.C. § 346(a), gives the Secretary *permission* to set up tolerances for added poisonous or deleterious substances which are required or cannot be avoided by good manufacturing practice," *id.* at 868, and held that the Secretary

could not be required to establish such tolerances for coal-tar colors.

The foregoing analysis of case law clearly demonstrates the Court of Appeals' error of summarily dismissing all precedent before it and provides sound justification for Petitioner's request that this Court reverse the Court of Appeals' unprecedented interpretation of the FDCA, which renders a substantial portion of our food supply adulterated and bars interstate shipment of such commodities.

CONCLUSION

For the reasons set forth herein, the National Peanut Council, Inc., as *amicus curiae* in support of Petitioner, respectfully urges this Court to reverse the Judgment and opinion of the United States Court of Appeals for the District of Columbia Circuit.

Respectfully submitted,

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No. 85-664

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

**On Writ of Certiorari To
The United States Court Of Appeals
For the District Of Columbia Circuit**

BRIEF OF SOUTH CAROLINA AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

No. 85-664

FRANK YOUNG, Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

**On Writ Of Certiorari To
The United States Court Of Appeals
For The District Of Columbia Circuit**

BRIEF OF SOUTH CAROLINA AS AMICUS CURIAE IN SUPPORT OF PETITIONER

STATEMENT OF INTEREST OF THE AMICUS CURIAE

On September 19, 1980, the State of South Carolina, together with its sister States of North Carolina and Virginia, formally petitioned the United States Food and Drug Administration (FDA) to approve a plan for the controlled and safe distribution of corn containing trace amounts of aflatoxin, a mold by-

product which develops on corn in the field. This plan would limit distribution of such corn to use in feed for mature, non-lactating livestock and poultry. Since scientific evidence establishes that corn containing low levels of aflatoxin can be safely used for these purposes, FDA approved the plan.

Community Nutrition Institute and others filed suit challenging this FDA action. South Carolina has appeared as *Amicus* supporting FDA in both the District Court and Court of Appeals proceedings. Although FDA's action was sustained by the District Court, the Court of Appeals found otherwise. The Court of Appeals held that FDA can allow shipment of product bearing a contaminant, such as aflatoxin, only if FDA first establishes formal tolerances pursuant to 406 of the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. § 346.

South Carolina is seriously concerned that, if this decision is upheld, the public health of the citizens of South Carolina will be jeopardized, added regulatory burdens on South Carolina will be imposed, and South Carolina's ability to coordinate with FDA on regulatory matters of common concern will be hindered. Thus, for the reasons and arguments which follow, South Carolina requests this Honorable Court to reverse the decision of the Court of Appeals.

A. Statement of Facts

Aflatoxin is a field contaminant that exists at very low levels on most field crops. However, not all levels of aflatoxin contamination pose a discernable risk to health. As with other environmental contaminants, FDA has made determinations on the basis of scientific evidence and its expertise as to what level of

aflatoxin contamination "may render it [the food] injurious to health." This is the adulteration standard under § 402(a)(1) of the Act, 21 U.S.C. § 342(a)(1).[1] FDA's determinations on the safety levels of environmental contamination of foods are commonly referred to as "action levels." In 1974, FDA published a general action level for aflatoxin on corn at 20 parts per billion (ppb). 39 *Fed. Reg.* 42748 (December 6, 1974).

In 1980, the corn crop of the Southeastern United States contained a higher than usual level of aflatoxin due to an unusual combination of early drought and late rains.[2] As a result of the unavoidable contamination, South Carolina, as well as two of its sister states, had to choose between obtaining FDA's cooperation in regulating the interstate use of corn with aflatoxin above 20 ppb or regulating the use and disposition of such corn solely within the border of the state. The States chose the first course.

South Carolina, together with North Carolina and Virginia, petitioned FDA to approve a plan for the controlled safe use of corn containing up to 100 ppb aflatoxin. Since corn with elevated levels of aflatoxin (100 ppb) can safely be used as feed for mature, non-lactating livestock and poultry, and since the States had adopted regulatory controls to ensure the corn would be used strictly for this purpose, the States submitted that corn with aflatoxin up to 100 ppb

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[1]Under this section a food is adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health. . . ."

[2]Approximately 70% of the crop exceeded the existing aflatoxin action level of 20 ppb.

would not be adulterated. After reviewing the States' petition, FDA agreed and approved the plans. 46 *Fed. Reg.* 7447 (January 23, 1981).

Notwithstanding FDA's and the States' conclusion that the plan complied with the FDCA, Community Nutrition Institute (CNI) then filed a suit challenging the plan approvals. CNI argued that FDA's authority to approve the plan regarding distribution of corn bearing aflatoxin in amounts of 20 - 100 ppb for certain feed uses was improper unless the Agency resorted to formal, trial type rulemaking pursuant to §§ 406 and 701(e) of the FDCA, 21 U.S.C. §§ 346 and 371(e).

B. Proceedings Below

The United States District Court for the District of Columbia heard this case on cross motions for summary judgment and granted the motion filed by FDA. The court correctly ruled that § 406 did not mandate tolerances for innocuous levels of unavoidable poisonous or deleterious substances.

The United States Court of Appeals for the District of Columbia Circuit reversed, holding that any product containing even innocuous levels of a poisonous or deleterious substance violates the FDCA, and therefore FDA cannot allow or sanction the shipment of products containing such contaminant until it first promulgates a tolerance pursuant to §§ 406 and 701(e) of the FDCA. In effect, the Court of Appeals decision struck § 402(a)(1) from the FDCA and overruled this Court's decisions in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958), and *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).

SUMMARY OF ARGUMENT

In its decision, the court below ruled FDA must promulgate a formal tolerance pursuant to § 406 of the Act before it can "authorize" the shipment of products containing innocuous levels of environmental contaminants. This ruling is in error because the court failed to recognize the principal role of § 402(a)(1) of the Act; it is this section which prescribes the basic and general test of food adulteration. In *Lexington Mill & Elevator*, this Court held that under § 402(a)(1) the mere presence of a poisonous or deleterious substance does not render a product adulterated; rather the substance must be present in such a quantity that the finished product may pose a danger to public health. The court below ignored this precedent and rewrote § 402(a)(1) so that now the mere presence of a contaminant is sufficient to render a product adulterated.

In addition to minimizing the scope of § 402(a)(1), the court below placed undue emphasis on § 406 and the establishment of tolerances. As this Court recognized in *Flemming v. Florida Citrus Exchange*, the purpose of § 406 is only to give sanction to what otherwise would be adulteration under § 402(a)(1).

By failing to appreciate the statutory scheme, the court below failed to recognize what FDA did in the present controversy. FDA did not authorize the shipment of adulterated food; rather, FDA recognized the limited use of corn containing up to 100 ppb aflatoxin would not constitute adulteration under § 402(a)(1), because the permitted uses in feed for mature, nonlactating livestock and poultry would be in no way

injurious to health. Since such products were not adulterated, the requirement of § 406 tolerances was never triggered. In sum, FDA acted properly.

ARGUMENT

I. TOLERANCES ARE NOT REQUIRED FOR FOODS WHICH CONTAIN INNOCUOUS LEVELS OF POISONOUS OR DELETERIOUS SUBSTANCES

In the decision below, the Court of Appeals failed to grasp the significance and role of § 402(a)(1) of the Act which proscribes as adulterated any food that contains poisonous or deleterious substances which may render the food injurious to health. By recognizing the scope of § 402(a)(1) and its interplay with § 406 of the Act, it becomes clear that the Court of Appeals' decision was wrong as a matter of law.

A. Section 402(a)(1) Is The Centerpiece Of The Act's Adulteration Provision

Section 402(a)(1) provides that a food will be deemed adulterated "if it bears or contains a poisonous or deleterious substance which may render the food injurious to health." This provision stands "as the Act's broadest and most general test of food adulteration. . . ." *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 161 (1958). Indeed, since it is the general adulteration standard, it governs unless expressly displaced by a more specific provision.[3]

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[3]Since 1938, Congress has adopted particular rules applicable to specific classes of substances which might be added to food, such as pesticides, food additives and color additives. In each case, Congress has exempted these substances from the general adulteration standard of § 402(a)(1). *See, e.g.*, § 408 of the FDCA, 21 U.S.C. § 346a (While a pesticide tolerance is in effect, the pesticide is exempt from § 402(a)(1)); § 409 of the FDCA, 21 U.S.C. § 348 (While a food additive regulation is in effect, the additive is exempt from § 402(a)(1)); § 706 of the FDCA, 21 U.S.C. § 376 (While a color additive listing regulation is in effect, the color additive is exempt from § 402(a)(1)). If § 402(a)(1) was not the general standard, these statutory exemptions of specific substances from its scope would be simply illogical.

This Court has interpreted the "may render it injurious to health" standard in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).[4] There, this Court stated that the mere presence of a poisonous or deleterious substance in food does not render the product adulterated; rather, the substance must be present *in such quantity* as may render it [the food] injurious to health.

> "This is the plain meaning of the words, and our view needs no additional support by reference to reports or debates, though it may be said in passing that the meaning which we have given to the statute was well expressed by Mr. Hayburn, Chairman of the Committee. . . . 'As to the use of the term "poisonous" let me state that everything which contains poison is not poison. It depends on the *quantity* and combination.' " Id. at 410 (emphasis added) (citation omitted).

Under the *Lexington Mill* test, the question of whether a product is adulterated is not as elementary as portrayed by the court below, *i.e.*, the court found

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[4]The *Lexington Mill* case involved § 7 of the Pure Food and Drugs Act of 1906 (34 Stat. 769) which was the predecessor provision to the current § 402(a)(1) of the Act. The § 7 language, as interpreted by this Court in *Lexington Mill*, retained its applicability and vitality even after the 1938 revision. *See, e.g., Flemming v. Florida Citrus Exchange, supra*, 358 U.S. at 161.

the mere presence of an unavoidable poisonous or deleterious substance adulterates the food which bears the substance. As this Court recognized, a more in-depth analysis is required under § 402(a)(1) to assess the risk to health based on the level of the substance in the food. Since the Court of Appeals misconstrued the role of § 402(a)(1) and its standard for adulteration, it failed to discern that provision's relationship to § 406. Thus, the decision below also misapplied § 406 by holding a formal tolerance is always required for aflatoxin in corn.

B. Section 406 Does Not Totally Address The Problem Of All Poisonous Or Deleterious Substances

In addition to retaining the "may render it injurious" standard of the Food and Drugs Act of 1906, the 1938 revision to the Act added both a new § 406, "Tolerance for Poisonous Ingredients in Food (§ 406(a)) and Certification of Coal Tar Colors for Food" (§ 406(b)) and a new § 402(a)(2), proscribing as adulterated any food unsafe within the meaning of § 406.[5]

The language which was adopted in § 406(a) of the 1938 Act covering tolerances, was recodified in the current § 406 to provide in relevant part, that:

> "Any poisonous or deleterious substance added to any food, *except where such substances are required* in the production thereof *or cannot be avoided* by good manufacturing practice shall be deemed to be unsafe for the purposes of the application of Clause 2 of § 402(a); but when such substance is so required or cannot be avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health. . . . *While such a regulation is in effect . . . such food shall not . . . be considered to be adulterated within the meaning of Clause 1 of § 342(a) of this title.*" (Emphasis added.)

[5] Section 402(a)(2) as enacted in 1938 read:

"If it bears or contains an added poisonous or added deleterious substance which is unsafe within the meaning of § 406."

By its plain language, this provision addresses two specific circumstances. The first sentence provides that the addition of any *unnecessary* or *avoidable* poisonous or deleterious substance, in any amount, renders the product adulterated under § 402(a)(2)(A) of the FDCA. It is important to note that such products are adulterated under § 402(a)(2)(A), not the general "may render injurious" standard of § 402(a)(1).

The second clause of the first sentence states that where the substance is necessary for production or unavoidable *and* a tolerance is in effect, any product which contains such substances in excess of the tolerance is adulterated under § 402(a)(2)(A). Yet, the section does not expressly address those situations where the substance is unavoidable and no tolerance has been established. Since such a situation can exist, witness the present case, it is clear that § 406 does not address every possible type of food contamination with poisonous or deleterious substances. Thus, the question becomes under which circumstances of food contamination with poisonous or deleterious substances does § 406 mandate the promulgation of a formal tolerance.

C. Tolerances Are Only Required When The Level Of A Contaminant Renders The Product Adulterated Under § 402(a)(1)

The starting point for determining when tolerances are required is the interplay between § 402(a)(1) and § 406. As discussed above, § 402(a)(1) is the general adulteration standard which will govern, unless displaced by specific statutory exemptions. Since § 406 does not address unavoidable contaminants in the absence of a tolerance, § 402(a)(1) governs as a matter of statutory construction and common sense. This conclusion is supported by the obvious omission in § 406 which fails to define as "unsafe" unavoidable contaminants when no tolerance is in effect. Thus, the § 406 companion adulteration provision, § 402(a)(2)(A), is not triggered. Indeed, Respondents concede that in the absence of a tolerance established under § 406, § 402(a)(1) applies to poisonous or deleterious substances.[6]

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[6]See, Respondents' *Opposition to Petition for Writ of Certiorari*, November 20, 1985, at 9. However, Respondents attempt to limit this concession by arguing that § 402(a)(1) is an interim provision to regulate poisonous or deleterious substances until a tolerance has been established under § 406. Such a position is unsupported in the statutory framework. *First*, § 402(a)(1) is not some uncodified provision, it is the topic sentence of the entire food adulteration provision, hardly a logical spot to place an interim provision. Indeed, as discussed above, it is the general test of adulteration. *Second*, when Congress has recognized the necessity of an interim provision, it has dealt with the issue in a separate provision which has not been codified within the Act. *See, e.g.*, 74 Stat. 404 (1960) (color additives); 72 Stat. 1788 (1958) (food additives); 68 Stat. 517 (1954) (pesticides). *Finally*, Respondents' position is flatly contradicted by this Court's opinion in *Flemming v. Florida Citrus Exchange*, where this Court recognized § 402(a)(1) as the broadest and most general adulteration standard, 358 U.S. at 161.

By recognizing § 402(a)(1) governs unavoidable contaminants not covered by tolerances, the purpose of § 406 becomes clear. The section authorizes FDA to establish tolerances to condone the presence of unavoidable poisonous or deleterious substances which otherwise would be adulterated under § 402(a)(1). This reading is supported by the plain statutory language and this Court's opinion in *Flemming*.

First, the very word "tolerance" indicates that Congress recognized what authority it granted FDA and when it should be exercised. The word "tolerance" is defined as "the allowable deviation from a standard." *Webster's New Collegiate Dictionary* (7th ed. 1969). By authorizing tolerances, Congress authorized FDA to allow deviation from the general adulteration standard of § 402(a)(1).

Second, the criteria for determining a tolerance level is more liberal than the general adulteration standard. Section 406 provides that in setting levels, FDA can consider the extent to which the contaminant cannot be avoided and the level necessary to protect the public health. This implies a balancing of the practicalities not permitted under § 402(a)(1). Such language would allow levels beyond which "may render the product injurious to health."

Third, the second sentence of § 406 exempts products for which a tolerance has been established from the general adulteration provision.[7] Only if the pur-

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[7]The language reads:

> "While such a regulation is in effect. . .such food shall not. . .be considered to be adulterated within the meaning of clause (1) of § 342(a) of this title."

pose of the tolerance is to condone that which is adulterated would it make any sense to exempt products for which a tolerance has been established from the general adulteration standard.

Finally, the above reading is supported by this Court's opinion in *Flemming v. Florida Citrus Exchange*. There, the Court held that § 406 carved out specific exemptions to the general adulteration provision found in § 402(a)(1). This Court found that the:

> "Existence of a tolerance is specifically stated in § 406(a) [currently 406] *only to give sanction to what would otherwise amount to adulteration within the terms of § 402(a)(1).*" 358 U.S. at 166 (emphasis added).

Accordingly, to determine whether FDA was required to proceed by formal tolerance in temporarily amending the aflatoxin in corn action level, it must be determined whether corn used as feed for mature, non-lactating livestock and poultry violates § 402(a)(1), as interpreted by this Court in *Lexington Mill*

II. INNOCUOUS LEVELS OF POISONOUS OR DELETERIOUS SUBSTANCES DO NOT AS A MATTER OF LAW RENDER FOODS CONTAINING SUCH SUBSTANCES ADULTERATED

The fatal flaw of the Court of Appeals reasoning is the presumption that any amount of a poisonous or deleterious substance renders the food adulterated. Pet. App. 7a. However, this presumption runs contrary to the language of § 402(a)(1) of the FDCA, as interpreted by this Court in *Lexington Mill.*

The question of whether the quantity of the contaminant is such that the substance may render it [the food] injurious to health and in violation of §

402(a)(1), is a question of scientific analysis requiring consideration of the substance's level in the food and its toxicological significance. The Court of Appeals, in holding that a food which contains any level of a contaminant is adulterated as a matter of law, wrote § 402(a)(1) out of the statute and overturned the *Lexington Mill* decision.

III. THE COURT OF APPEALS, BY IGNORING SECTION 402(a)(1) AND THE SUPREME COURT'S DECISION IN *LEXINGTON MILL*, MISCONSTRUED FDA'S ACTION IN THIS CONTROVERSY

The court below erroneously concluded that a major portion of the 1980 South Carolina corn crop was adulterated because it contained low levels of aflatoxin, *i.e.*, between 20 - 100 ppb. From this mistaken assumption, the court mandated that FDA was required to regulate this commodity by establishing a formal tolerance. The Court of Appeals erroneously concluded that FDA by raising the aflatoxin action level to a maximum of 100 ppb for certain animal feed purposes was "condoning" a violation of the Act.

However, this holding misconstrues what FDA actually did. FDA had focused on whether corn containing up to 100 ppb of aflatoxin, when strictly limited to uses in animals feed for mature, non-lactating livestock or poultry would pose a risk to health. On the basis of FDA's scientific review, it determined that corn containing up to 100 ppb aflatoxin could be safely used for this limited purpose. By making such a finding, FDA concluded that the corn for the limited purpose was *not* adulterated under § 402(a)(1).[8]

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[8]It is important to emphasize FDA did *not* modify its general

Since the South Carolina corn was found not to be adulterated, the tolerance setting procedures of § 406 were never called into play. Thus, FDA was not mandated to establish a tolerance since there was simply no violation to "condone." *Flemming v. Florida Citrus Exchange*, 358 U.S. at 167.

IV. THE COURT OF APPEALS DECISION THREATENS SOUTH CAROLINA'S ABILITY TO PROTECT ITS CITIZENS

A. The Decision Increases Risk To Public Health Of The Citizens Of South Carolina

The effect of the Court of Appeals decision is to prohibit the shipment in interstate commerce of any food which contains any level of an unavoidable poisonous or deleterious substance. In an effort to protect the public health, the Court of Appeals has actually jeopardized it. The shipment in interstate commerce of an "adulterated" food is prohibited under the FDCA.[9] Thus, contaminated agricultural commodities, "adulterated" under the Court of Appeals' decision, must remain within the state of their origin, and states, such as South Carolina, would be responsible for the entire regulatory burden of ensuring the safe use of the product. This would be virtually impossible for a state such as South Carolina because

action level for corn (20 ppb) applicable to all uses of corn, *i.e.* human use. This general level would apply to corn unless specifically exempted for the special use as feed of mature nonlactating livestock and poultry.

[9]FDA's authority to regulate or prohibit the shipment of adulterated food is limited to either the interstate shipment of the product or movement of the components of the food product in interstate commerce. See §§ 301(a) & (k) of the FDCA, 21 U.S.C. § 331(a) & (k).

no one state could necessarily consume the millions of pounds of a raw agricultural commodity dedicated to safe uses in animal feed.

The Court of Appeals stated that these problems could be overcome if FDA established tolerances. Ignoring the question of whether tolerances can take many years to be established, a tolerance lacks the flexibility either to respond to a request for modification in light of unforeseen circumstances, such as the South Carolina 1980 request, or to tighten the tolerances in light of new scientific data to better protect the public health. States, such as South Carolina, should not be forced to wait many years to obtain FDA guidance as to whether a perishable product violates § 402(a)(1); nor should the public be exposed to ten years of unsafe use while a formal tolerance is being revised to reflect new scientific data showing the substance to be more harmful than first perceived.

B. The Court Of Appeals Decision Denies Guidance To The States

In the past, South Carolina has come to rely on FDA's expertise and resources in determining what constitutes adulteration under § 402(a)(1). However, the Court of Appeals decision would prohibit FDA from giving guidance in this area since such guidance could be construed as an "impermissible action level." It is unsound public policy to prohibit Federal and State agencies from exchanging information to better serve the public health. Because the agricultural and food industries operate on a national level, food safety questions are often best solved on the national level. Denying the States the ability to work with FDA to solve a food safety problem balkanizes solutions,

makes them less than adequate and places the public health in jeopardy.

CONCLUSION

For the above reasons, the State of South Carolina respectfully requests this Honorable Court to reverse the decision of the Court of Appeals for the District of Columbia Circuit.

Respectfully submitted,

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